U.S. Department of Health and Human Services

National Institutes of Health

# Twenty-Fifth Meeting of the Clinical Center Research Hospital Board

**October 20, 2023**

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## Clinical Center Research Hospital Board

Norvell V. Coots, M.D., President and Chief Executive Officer (CEO), Holy Cross Health, and Chair, National Institutes of Health (NIH) Clinical Center Research Hospital Board (CCRHB)

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Tara A. Schwetz, Ph.D., Acting Principal Deputy Director, NIH, and Executive Secretary, CCRHB

David M. Baum, PMP, NIH Research Participant and Patient Advocate

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, 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 A. Freischlag, M.D., Dean, Wake Forest University School of Medicine

Steven I. Goldstein, M.H.A., President and CEO, Strong Memorial Hospital, University of Rochester Medical Center

Jack Leslie, Former Chairman, Weber Shandwick, Senior Visiting Fellow, Duke Global Health Institute

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

Antoinette Royster, NIH Research Participant and Patient Advocate

Craig E. Samitt, M.D., M.B.A., Founder and CEO, ITO Advisors

## Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 25th meeting in person and via videoconference on October 20, 2023. The meeting was webcast live and open to the public. A video recording is available online.

Norvell V. Coots, M.D., President and Chief Executive Officer (CEO) of Holy Cross Health and Chair of the CCRHB, called the meeting to order at 9:00 a.m. ET. He welcomed everyone to the meeting and indicated who was attending in person and who was attending virtually.

Lawrence A. Tabak, D.D.S., Ph.D., Acting Director of NIH and Executive Director of the CCRHB, highlighted changes in NIH leadership and updated the CCRHB on progress of the nomination of Monica M. Bertagnolli, M.D., for the position of NIH Director. In addition, Dr. Tabak announced names of NIH staff who recently received awards recognizing their scientific accomplishments. NIH is seeking public comment on a change to the NIH mission statement to better reflect diverse viewpoints of disability communities. Dr. Tabak noted that Long COVID imposes a heavy burden across the nation, necessitating coordinated extra- and intramural research strategies. He also presented a new framework for scoring grant applications that de-emphasizes the reputation of the investigator and their institution while elevating the importance of the research and the rigor and feasibility of the proposed approach. The new framework will be implemented on January 25, 2025.

James K. Gilman, M.D., CEO of the NIH Clinical Center (CC), announced various honors given to NIH employees in recent months. He also described progress in construction of the new Surgery, Radiology, and Laboratory Medicine wing. He announced that the average daily census for 2023 is about the same as it was in 2022, but the 3-year average remains lower than it was before the pandemic. The inpatient census is up 7%, but the average length of stay is down 11%. The number of outpatient visits is up 8%. About 10% of visits are by telehealth. He updated the Board on patient satisfaction and safety statistics, as well as progress in the area of diversity, equity, inclusion, and accessibility.

Jack Shern, M.D., of the National Cancer Institute's Pediatric Oncology Branch, is the medical director for Camp Fantastic, which started in 1983 and is the longest-running active protocol in the Clinical Center. Camp Fantastic is held at the 4-H Center in Front Royal, Virginia. Dr. Shern described it as a beautiful facility located on a large property, complete with stables, a lake, a pool, and a firepit. About 100 children usually take part in the weeklong overnight camp, which is held in August each year. Campers' medical needs vary from minimal to extensive. Running the camp requires about 45 medical staff who monitor the campers' health and deliver health care as needed. The 2023 camp presented special challenges because of a lack of coverage for volunteer staff under the Federal Tort Claims Act.

Barbara Jordan, DNP, RN, NEA-BC, was recently appointed as the Chief Nurse Officer for the Clinical Center. Dr. Jordan updated the CCRHB on progress with Magnet® accreditation and presented a timeline with milestones. The Magnet® team is working on the document that will be submitted to the American Nurses Credentialing Center (ANCC) in April 2024. The hope is that the ANCC appraisers will score the document as acceptable and then schedule a site visit. Dr. Jordan also described events held in the CC to promote the Magnet® journey and presented metrics that will be used to show that the CC meets or exceeds standards.

Jon McKeeby, D.Sc., M.B.A., Chief Information Officer of the Clinical Center, explained the hospital's existing electronic health record system—the Clinical Research Information System (CRIS), which has been in place for 19 years (since 2004). He outlined the features and deficiencies of CRIS and identified requirements. Work is underway on the statement of work and the performance work statement for acquiring a new system that can meet the needs of the CC, the 27 NIH Institutes and Centers, and patients. The main hurdle is the funding.

Ann Berger, M.D., M.S.N., Chief of the Pain and Palliative Care Service; and John M. Pollack, M.Div., BCC, Chief of the Spiritual Care Department, spoke about the Wellness Initiative at the NIH Clinical Center. The initiative is built upon evidence-based frameworks for reducing clinician burnout and stress while boosting staff morale and enthusiasm for their work. The Wellness Initiative focuses mainly on identifying respite care and peer support programs that already exist in CC departments and then expanding the programs to other services or departments.

Andrew B. Singleton, Ph.D., is the Director of the Center for Alzheimer's and Related Dementias (CARD), an intramural initiative of the National Institute on Aging in collaboration with the National Institute of Neurological Disorders and Stroke. CARD's mission is to "Initiate, stimulate, accelerate, and support research in AD/ADRD [Alzheimer's disease/Alzheimer's disease–related dementias], leading to the development of improved treatments and preventions for these diseases." CARD projects range from basic science to clinical translational studies. Dr. Singleton described several CARD projects and showed how they fit within the Center's scientific priorities.

Dr. Coots adjourned the meeting at 12:57 p.m. The next meeting of the CCRHB is slated for February 16, 2024.

# Meeting Summary
## October 20, 2023

## Welcome and Board Chair's Overview

*Norvell V. Coots, M.D., President and Chief Executive Officer (CEO), Holy Cross Health, and Chair, NIH Clinical Center Research Hospital Board (CCRHB)*

Dr. Coots welcomed everyone—including NIH leaders and staff and members of the public—to the meeting, which was conducted in a hybrid format.[*] In addition to Dr. Coots, the following Board members attended the meeting in person: David Baum, PMP; Jack Leslie; Stephanie Reel, M.B.A.; Antoinette Royster; and Craig E. Samitt, M.D., M.B.A. The following members participated via the virtual meeting platform: David C. Chin, M.D., M.B.A.; Regina S. Cunningham, Ph.D., RN, FAAN; Sherin U. Devaskar, M.D.; Julie Freischlag, M.D.; and Steve Goldstein, M.H.A. Also present in person were Lawrence A. Tabak, D.D.S., Ph.D., Executive Director of the CCRHB, and Tara A. Schwetz, Ph.D., Executive Secretary of the CCRHB.

Dr. Coots announced that the CCRHB charter was recently amended. The updated charter was sent to members earlier in the week and will be posted on the CCRHB website soon. The main change was to the Board's operating budget, which will now provide honoraria to members for meeting attendance.

Dr. Coots also acknowledged that we are living in extraordinary times, with an ongoing war between Ukraine and Russia, and, for the past 2 weeks, the latest war between Israel and Hamas.

## NIH Director's Remarks

*Lawrence A. Tabak, D.D.S., Ph.D., Acting Director, NIH, and Executive Director, CCRHB*

### *NIH Leadership Changes*

Dr. Tabak announced several key changes in NIH leadership:

- Monica M. Bertagnolli, M.D., was nominated by President Joe Biden for the position of NIH Director. She is currently the Director of the National Cancer Institute. She had her hearing at the Senate Health Committee meeting this week. Chair Bernie Sanders indicated that the committee will vote on the nomination on October 25, 2023. If all proceeds smoothly, Senate confirmation could occur in early November.
- The new Director of the National Institute of Allergy and Infectious Diseases (NIAID) is Jeanne M. Marrazzo, M.D., M.P.H., from the University of Alabama Division of Infectious Diseases. Dr. Tabak thanked Hugh Auchincloss, M.D., who served as NIAID's Acting Director.
- Patricia Flatley Brennan, RN, Ph.D., retired from her position as the Director of the National Library of Medicine (NLM). She emerged as an NIH leader in the digital space and helped guide NIH in strategic ways. Stephen Sherry, Ph.D., who currently heads the

[*] The meeting was videorecorded; the recording is available online.

National Center for Biotechnology Information at NLM, is stepping in as Acting Director until a new director is named.

- Lauren Higgins has been serving as the Acting Associate Director for Legislative Policy and Analysis of the Office of Legislative Policy and Analysis, but Katherine (Kate) Klimczak has accepted the position of permanent Associate Director.
- Andrew A. Bremer, M.D., Ph.D., was recently appointed as Director of the Office of Nutrition Research. Dr. Tabak spoke about the need for doing more in the field of nutritional science. The Office of Nutrition Research is part of the Division of Program Coordination, Planning, and Strategic Initiatives, a large division within the NIH Office of the Director that comprises 14 different offices.

***Proposed Revision of the NIH Mission Statement***

Dr. Tabak compared the current mission statement and the proposed revision:

- **Current statement:** "NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and *the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.*"
- **Proposed revision:** "NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and *to apply that knowledge to optimize health and prevent or reduce illness for all people.*"

The impetus for the revision came from the disability community, which pointed out that some of them do not require redress of their condition or capabilities. An example is the deaf community; many deaf people feel that they do not need to be "fixed." The disability community is a highly heterogeneous group, and many among them view NIH's current mission statement as ableist.

Dr. Tabak announced that a request for information (RFI) is inviting public comment on the proposed revision through November 24, 2023.

- **ACTION ITEM:** Dr. Tabak asked the Board members to invite their colleagues to weigh in on the revised mission statement via the RFI before the closing date of November 24, 2023.

***Long COVID***

Dr. Tabak explained that Long COVID, also called post-acute sequelae of COVID-19 (PASC), affects many systems of the body and causes a wide spectrum of symptoms. Because of this, a comprehensive approach involving both extramural and intramural research efforts is needed to understand Long COVID and develop ways to predict, treat, and prevent it.

In the extramural space, NIH is supporting the Researching COVID to Enhance Recovery (RECOVER) Initiative, which covers multisite adaptive clinical trials. Dr. Tabak noted that many people with Long COVID, as well as their caregivers and advocates, have become experts and can offer their expertise to inform research. By using an adaptive platform, the investigators can apply new approaches if the science evolves.

Dr. Tabak pointed out a study funded in part by NIAID that was published in *Cell*. The findings suggest that reduced levels of circulating serotonin may play a role in PASC, although this effect appears to apply to only certain subsets of patients.

Due to repeated mutations, the SARS-CoV-2 strain currently prevalent is not the same as the ancestral strain, so developing treatments requires adapting based on patient responses, different viral strains, and other variables. The RECOVER investigators are planning five clinical trials, two of which are enrolling participants or are nearly ready to do so. The trial that has begun enrollment is investigating whether reduction of viral load plays a role in recovery. Another, which will start enrollment soon, aims to ascertain approaches for dealing with some neurologic and cognitive dysfunctions that have been reported.

Dr. Tabak said that sequelae of viral infections are well known. For example, both Long COVID and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) are linked with viral infections and are characterized by cardiopulmonary exercise intolerance and fatigue. For at least some subsets of CFS/ME patients, exercise can exacerbate the condition. NIH is working with several groups to learn more about the role of exercise during recovery from Long COVID; supervised exercise might be a promising strategy.

In terms of intramural research, Dr. Tabak mentioned a longitudinal study by NIAID that has been tracking COVID-19 sequelae since June 2020. Another intramural study, COVID-19 ARC (Acute, Recovery, Convalescence), is focusing on a population with a high burden of persistent symptoms. The hope is that investigating the most severe cases will provide greater insights into the disease.

Dr. Tabak discussed links between neurologic symptoms in Long COVID and structural changes in the brain. The plasma protein profile was quite altered among 100 Long COVID patients who had brain imaging studies done. Nina Schor, M.D., Ph.D., Deputy Director for Intramural Research at NIH, said that it is possible to demonstrate SARS-CoV-2 persistence in the central nervous system of some patients. Dr. Tabak added that autopsy studies reveal brain damage associated with inflammation, especially around blood vessels.

All these findings underscore the great heterogeneity among Long COVID patients. Dr. Tabak said that the extramural program's flexibility allows the program to carry out clinical trials productively, in ways that complement the intramural program, which can pivot quickly and carry out longer-term studies.

***Changes to Peer-Review Criteria for Application Scoring***

Dr. Tabak presented five criteria, each scored individually, currently used to score grant applications:

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Under the current framework, reviewers tended to give more weight to applicants who work at famous institutions. Dr. Tabak then presented the new framework, which was designed to de-emphasize the reputation of the investigator and their institution in the scoring:

- **Factor 1: Importance of the Research:** This criterion is scored individually and is based on significance and innovation.
- **Factor 2: Rigor and Feasibility:** This criterion is also scored individually and reflects the research approach.
- **Factor 3: Expertise and Resources:** This factor is not scored individually; rather, it is evaluated only for sufficiency. Dr. Tabak said that the facility and personnel either are adequate or are not. Criteria apply to the investigator(s) and the research environment.

This new framework will be implemented on January 25, 2025. The research community is very enthusiastic about the change.

## NIH Clinical Center (CC) CEO Update

*James K. Gilman, M.D., CEO, NIH CC*

Dr. Gilman congratulated Dr. Coots, the CCRHB Chair, who was recently recognized by *Becker's Hospital Review* as one of the top physician leaders in the country. He is also now a member of the American Hospital Association's board of trustees.

Dr. Gilman acknowledged some accomplishments of NIH personnel:

- Barbara Jordan, DNP, RN, NEA-BC, was appointed as Chief Nurse Officer (CNO) in July 2023 after serving as Acting CNO for 2 years.
- A new exhibit in the CC honoring Harvey Alter, M.D., was recently unveiled. Dr. Alter was one of three researchers to share the 2020 Nobel Prize in Physiology or Medicine for the discovery of the hepatitis C virus. Dr. Alter is the sixth NIH scientist to win a Nobel.

### *Recent CC Grand Rounds*

Dr. Gilman spoke about the importance of medical simulation and the presentation "Health Care Simulation's Role in Building Team Cognition," delivered during Health Care Simulation Week (September 18–22, 2023). Dr. Gilman said the goal for senior staff—even world-renowned experts—should be to leave the simulation "at least 1% better." The goal of the enhanced simulation center, as described on page 16 of the Clinical Center's 2019 Strategic Plan, is to identify CC resources and a new location.

### *Surgery, Radiology, and Laboratory Medicine (SRLM) Wing*

The groundbreaking ceremony for the SRLM wing occurred on May 16, 2023, and the building is now taking shape. Excavation is underway. A dump truck full of dirt departs the construction site about every 3 minutes when activity is in full swing. Recently, visitors from the Senate Committee on Health, Education, Labor and Pensions wanted to see the progress on the SRLM. The Office of Research Facilities brought them on a tour at ground level, and Dr. Gilman brought them up to the fifth floor for an aerial view.

*Special Events*

- **Dedication event for the Clinical Center's Lionel Bernstein sculptures.** Dr. Bernstein, a gastroenterologist who worked for a time at the Clinical Center, started creating wooden sculptures after he retired. Dr. Bernstein passed away in March 2019 at the age of 95, and his family donated several sculptures to the Clinical Center.
- **The Clinical Center Nursing Department (CCND) "Men in Nursing" event.** On September 27, 2023, Ernest Grant, Ph.D., RN, FAAN, and past President of the American Nurses Association, delivered a presentation for the event. A panel of male nurses also offered inspiring stories. The event was well attended and well received.
- **September 13, 2023, Clinical Center Grand Rounds.** David K. Henderson, M.D., formerly the CC's Chief Medical Officer and now a consultant to the CC, delivered an address, "The COVID-19 Pandemic: Looking Back and Looking Forward."

*Hospital Census*

Dr. Gilman reported that the average daily census (ADC) has been quite stable but is still below the 3-year average ADC, which includes 2019 and the early part of 2020 (pre-pandemic). The statistics for inpatient days in 2022 and 2023 are similar. In 2023 thus far, admissions are up by 7% but average length of stay is down by 11%. In-clinic outpatient visits are up by 8%. About 10% of visits are by telehealth, totaling about 600 telehealth encounters per month.

Dr. Gilman said that the CC has returned to normal operations, similar to how it was run before the pandemic. Now, with no dedicated testing areas for staff, use of the metabolic inpatient unit has been restored.

*Diversity, Equity, Inclusion, and Accessibility (DEIA) Updates*

CC staff and leaders continue to focus on DEIA. Dr. Gilman highlighted some accomplishments in this area:

- The Clinical Center has to communicate with the NIH Office of Equity, Diversity, and Inclusion (EDI) about the Center's progress on its Racial Ethnic Equity Plan. This year, the CC completed a self-assessment of progress and submitted the results to the EDI, which will provide feedback on the documentation.
- A new CCND hiring and interview policy was initiated.
- The CC DEIA Advisory Committee became more active during the course of the year. The Committee is working on setting up an awards program.
- CC staff recently honored three national commemorations: National Hispanic Heritage Month, National Disability Employment Awareness Month, and Native American/American Indian Heritage Month.
- As Dr. Tabak noted, NIH is starting to think differently about disability and is departing from the medical model and moving toward a societal model. People's tendencies are sometimes overtly and sometimes subconsciously toward ableism. On July 17, 2023, the CC held a program entitled, "Ableism: Acknowledging It and How to Become Anti-Ableist."

- Regarding potential health disparities in the CC, Colleen Hadigan, M.D., has started looking at some of the data. Because the CC is not part of a health system, it is challenging to figure out how to analyze data, but Dr. Hadigan is working with some information technology/data management staff to come up with an analytical approach. Dr. Gilman discussed plans to present the data to the CCRHB early in 2024. The Accreditation Council for Graduate Medical Education and the Joint Commission are both interested in seeing the CC's disparities data and tracking progress.

***Clinical and Safety Performance Metrics***

The quarterly executive dashboard was distributed to the CCRHB in advance of the meeting and is also posted on the Board's website. Any questions should be directed to David Lang, M.D., M.P.H., Chief of the CC's Office of Patient Safety and Clinical Quality.

***Patient Satisfaction Surveys***

Dr. Gilman reported that patient satisfaction numbers continue to look very good. CC staff and leaders continue to seek opportunities for improvement by talking to patients and families whose experiences were not ideal. Dr. Hadigan and others review the narrative comments to identify ways to improve patient satisfaction.

Dr. Gilman discussed plans to field the Hospital Survey on Patient Safety Culture. This is a very important survey, and the CC is looking for an opportune time to deploy it. This survey was last fielded in 2017.

- The Agency for Healthcare Research and Quality (AHRQ) Survey on Patient Safety Culture was deployed in the CC in 2017 and 2020. This survey includes items on physical and psychological safety of staff. The topics covered by the survey include teamwork, staffing and work pace, response and communication on errors, and reporting of patient safety events. The plan is to open the online survey for 4 weeks in September–October 2023.
- AHRQ's hospital workplace safety supplemental set addresses protection from workplace hazards, workplace aggression from patients or visitors, and hospital management for workplace safety.
- Some results of the Federal Employee Viewpoint Survey (FEVS) are now available. Dr. Gilman said that the CC set a new record for participation. He expects to report FEVS results to the CCRHB early next year.

***Fiscal Year 2024 Budget***

The thinking is that the budget will be austere. The goal is to hold the gains made in terms of patient safety, patient experience, and patient care over recent years. Dr. Gilman did not envision any plans for "bright, shiny objects" in the coming year, and NIH will have to pivot to the priorities of the new NIH leadership.

Some funds remaining from last year are being applied to two new projects, the first of which aims to better assess and manage nursing workloads. Many CC patients are enrolled in highly complex protocols that translate into a tremendous nursing workload.

The CC budget has been approved by the Clinical Center Governing Board. The budget will go through the NIH Steering Committee and finally to the full body of Institute and Center Directors.

***Congratulations to Breakthrough Prize Recipients***

In closing, Dr. Gilman congratulated one of the day's speakers. Andrew B. Singleton, Ph.D., is an NIH distinguished investigator and heads the NIH Center for Alzheimer's and Related Dementias (CARD) within the National Institute on Aging (NIA). Dr. Singleton and another NIH researcher, Ellen Sidransky, M.D., a pediatrician and clinical geneticist with the National Human Genome Research Institute, each received a 2024 Breakthrough Prize in Life Sciences. The prize, considered to be Silicon Valley's answer to the Nobel, recognizes "transformative advances toward understanding living systems and extending human life."

## Camp Fantastic 2023

*Jack Shern, M.D., Lasker Clinical Research Scholar; Medical Director, Camp Fantastic; Pediatric Oncology Branch, Center for Cancer Research, National Cancer Institute*

Dr. Shern's presentation focused on Camp Fantastic, which started in 1983 and is the CC's longest-running active protocol. Tom and Sheila Baker, who lost their young daughter Julie to lymphoma, started the camp in 1982. They partnered with the CC to make Camp Fantastic a reality. Dr. Shern is the camp's current Medical Director.

Dr. Shern identified three main benefits of Camp Fantastic:

- Participants have fun, interact with peers, and gain confidence in themselves, all of which help improve their lives.
- The health care team's morale improves from seeing their patients in a new light. Caring for these young patients is hard work and emotionally grueling. While the participants are interacting with their peers and doing activities like riding horses or taking part in talent shows, the health care team gets to know patients as camp participants.
- Families benefit from the camp, which provides a respite for the parents or other family members who care for these medically complex children.

***About the Camp***

Camp Fantastic is held at the 4-H Center in Front Royal, Virginia. Dr. Shern said that it is a beautiful facility located on a large property, complete with stables, a lake, a pool, and a firepit. The campers stay in cabins. About 100 children usually take part in the weeklong camp, which is held in August each year.

The campers come from multiple centers throughout the Mid-Atlantic, including some smaller institutions and busy clinical centers, such as INOVA, Johns Hopkins University, and Children's National.

Camp Fantastic 2019 was the last pre-COVID camp. The camp was shut down during the summers of 2020, 2021, and 2022 because of the need to protect these vulnerable patients from COVID-19. Instead, the children participated in various activities over Zoom. Staff shipped craft kits to the campers. The "remote" camp was very popular and may be continued in the future to expand participation.

Dr. Shern provided some specifics about planning and logistics for Camp Fantastic. About 45 medical staff participate to make the Camp work. They set up a pediatric oncology clinic that is equipped with a pharmacy stocked with intravenous antibiotics and any therapies that the children are taking, a laboratory, and emergency equipment. Each day, NIH staff deliver needed items from the CC. Pediatric nurses can give chemotherapy regimens at camp.

Every department of the CC makes a contribution in terms of bed linens, pharmacy and laboratory support, and even the Department of Transfusion Medicine, which is able to give platelet infusions at camp.

The medical staff is a core group that is highly dedicated to providing the medical care for campers. CC staff from the Pediatric Oncology Branch and the CCND make the camp possible. Also, special volunteers, who are vital to the camp, include nurses who provide care for the campers from their institutions. Three times per day the patients go through Med Line where they take their prescribed medicines and check in with the nurses and doctors. Staff take care of a lot of bumps and bruises, and the campers go through a great deal of sunscreen and insect repellent. In addition, staff serve as "parents" at camp to help with homesickness and conflicts.

Dr. Shern said that the campers enjoy the entertainment. They like to see doctors break eggs over their heads. The talent show is a perennial favorite. Canoeing and fishing on the lake are popular, as is wading in a stream to look for "creek critters." The science program teaches campers about DNA and other topics. Horseback riding and woodworking are also available.

In closing, Dr. Shern encouraged the Board to support Camp Fantastic and get involved. One evening per camp session is set aside as visitors night.

***Discussion***

- Dr. Devaskar asked whether similar camps are held elsewhere. Dr. Shern said that an organization called the Children's Oncology Camping Association organizes camps across the country. Many major pediatric oncology centers run such camps, and information is shared across camps.
- Dr. Devaskar asked whether the funding for the camp is entirely from NIH. Dr. Shern said that the medical support comes from the CC. A 501(c)(3) organization called Special Love for Children with Cancer is in charge of the programming and also helps with logistics. They are a major partner and a big part of the funding stream.
- Dr. Reel volunteered to drive supplies from the CC to the camp.
- Dr. Gilman said that Camp Fantastic is a paradigm for how the CC does research: Plan, over-resource, and put contingency plans in place. That is a perfect paradigm for high-risk, first-in-human protocols. The camp does every year what the CC does with every new protocol.
- Dr. Gilman discussed recent challenges of staffing the camp. Due to some interpretations of the Federal Tort Claims Act (FTCA), NIH can no longer assure volunteers that they will be covered by the Act. NIH is trying to change this situation, which pertains to many other CC activities, too, as special volunteers help with many protocols. Volunteers are very important, and NIH has to be able to reassure them that they will be covered by FTCA.

- Ms. Royster asked about the implications if a volunteer is not covered by FTCA. Dr. Gilman explained that the volunteer would not be covered should someone file a lawsuit or a claim that involved any action the volunteer was involved in. Other federal agencies have been able to get FTCA coverage for volunteers codified in law, and NIH leaders are driving an effort to get the same protection for NIH's special volunteers, mainly the individuals who have clinical roles. Dr. Schor added that it would take legislative action to provide FTCA protections for NIH special volunteers. Once NIH has a Director and the House of Representatives has a speaker, this action might be feasible. Dr. Shern reported that for the 2023 camp, NIH staff had to provide the necessary staffing when it became clear that the volunteers would not be covered by FTCA.
- Mr. Baum asked whether the Friends of Patients at the NIH organization provides any support for Camp Fantastic. Dr. Gilman was not sure.
- A meeting participant asked what the campers' favorite activities are, and Dr. Shern said that they were horseback riding and swimming in the pool.
- **ACTION ITEM:** Dr. Gilman will find out whether the Friends of Patients at the NIH group is involved with Camp Fantastic and report back to Mr. Baum.

## Updates: The CC's Magnet® Accreditation Journey

*Barbara Jordan, DNP, RN, NEA-BC, CNO, NIH CCND*

Dr. Coots congratulated Dr. Jordan for her recent appointment as CNO of the Clinical Center. Dr. Jordan updated the CCRHB on the progress with Magnet® accreditation and presented a timeline with milestones.

The CCND signaled its intention to apply for Magnet Recognition® in January 2023, and now the team is writing the application in such a way that it tells the story of the CC and its unique role as a research hospital. The plan is to submit the application to the American Nurses Credentialing Center (ANCC) in April 2024. The hope is that the ANCC appraisers will score the document as acceptable and then schedule a site visit. The Magnet® Model has four domains: transformational leadership; structural empowerment; exemplary professional practice; and new knowledge, innovations, and improvements. Each domain has standards which will include one or more examples of how the CC supports the standard.

Dr. Jordan shared a sample of a standard and a supporting example of nurses participating as part of an interprofessional team and applying available resources to address ethical issues related to clinical practice. The example involved a patient on radiation isolation who was also paraplegic and therefore required a great deal of hands-on care despite radiation isolation. The nurses worked with the ethics team to ensure that the CCND was meeting patient needs while maintaining staff safety. The patient was grateful to take part in the study and also for the compassionate care she received.

### *Staff Engagement with the Magnet® Journey*

Dr. Jordan highlighted efforts to ensure that everyone in the CC and the NIH Institutes and Centers (ICs) is aware of the Magnet® journey. The Magnet® team started a rounds program, with the goal of reaching the majority of front-line staff on weekdays, nights, and weekends. A Magnet® fair is scheduled for October 26, to be run by the CCND's Magnet® Ambassadors for

education and engagement. The fair is being set up as a journey with "passports" that visitors can get stamped at various stations.

***Magnet® and Patient Engagement Metrics***

The Magnet® team plans to use the Press Ganey survey results to measure patient engagement. The plan is to select four of nine categories for both inpatient units and ambulatory settings, with the expectation that the majority of units have to exceed the national average. The following inpatient Magnet® categories were selected: courtesy and respect, patient engagement or patient-centered care, responsiveness, and safety. The expectation is that for each patient satisfaction category chosen, the majority of the units must outperform the national mean, median, or other measure of central tendency for the majority of eight quarters.

Dr. Jordan presented a table showing three questions under courtesy and respect. For all the inpatient areas, for the eight eligible CC units, the standard is being met at 100%, but Dr. Jordan cautioned that results can change. It is necessary to continually review the data to ensure the CC continues to meet patient needs.

For the ambulatory Magnet® categories, Dr. Jordan said that four different areas were selected: care coordination, careful listening, safety, and service recovery. In the safety category, there are four questions about safety: wearing of identification badges, staff handwashing, degree of safety and security, and skill of staff. The standard is being met at 100%. All 16 of the Magnet®-eligible ambulatory units are Magnet®-ready.

Dr. Jordan acknowledged all the staff involved in data collection and analysis.

***Discussion***

- Mr. Baum asked whether the standards, goals, and patient experience survey results are made readily visible to staff by being displayed on screen savers and electronic information boards. Heightened visibility could encourage staff and build awareness. Dr. Jordan thanked Mr. Baum for the suggestion. The data on patient experience are available on the intranet. The CCND works closely with Press Ganey through the CCND and the CC to teach nurse managers to understand and disseminate the data on the patient experience.
- Dr. Samitt asked which standards are the most distinctive for NIH as compared with other Magnet® institutions. Which standards are the most challenging? Dr. Jordan said that the chapter on new knowledge, innovation, and improvement is where nursing research and evidenced-based projects are discussed. That chapter is nearly done, thanks in large part to the research done by Gwen Wallen, Ph.D., RN, and the Translational and Biobehavioral Health and Disparities Research Branch. The Magnet® team has access to data from nursing research that includes outcomes data.
- Dr. Reel asked Dr. Jordan whether she has considered how to tie together the patient engagement and safety survey results. Are engaged units also safe units? Dr. Jordan said that the Magnet® team does not have those two instruments correlated. FEVS data are at the unit level, but the Culture of Safety Survey is open to everyone at the CC. Different people would be responding to those surveys, but it would be interesting to look for correlations.

- Dr. Chin recalled that, nationally, clinician burnout is a major issue. How might that affect the accreditation process for the CC? Dr. Jordan said that, like most other hospitals, the CC has staffing and recruitment issues. The Magnet® journey has rallied the nurses and all CC staff because it is their hard work and their accomplishments that are being catalogued in the Magnet® document. The Magnet® journey can be a morale booster. The 2021–2022 CCND annual report garnered highly positive feedback for nurses and staff throughout the CC.
- **ACTION ITEM:** Dr. Reel suggested that the Magnet® team consider how to tie together the patient engagement and safety survey results. Are engaged units also safe units?
- **ACTION ITEM:** Dr. Jordan volunteered to provide the CCRHB with the link to the 2021–2022 CCND annual report.

## Electronic Health Record (EHR) Modernization

*Jon McKeeby, D.Sc., M.B.A., Chief Information Officer, Department of Clinical Research Informatics, NIH Clinical Center*

Dr. McKeeby credited Jeffery Sano, D.N.P., M.S.N., Deputy Chief Information Officer, Clinical Informatics, NIH, for helping to create the slides for the presentation. Dr. Sano also helped produce many of the documents needed as part of the EHR modernization effort.

Dr. McKeeby explained that the Clinical Research Information System (CRIS) is a high-value asset. The Department of Homeland Security went through all the government's systems and identified high-value assets. By their assessment, CRIS was in the top 10% of high-value assets. The U.S. Department of Health and Human Services (HHS) then decided that CRIS and the systems for the Indian Health Service and the Centers for Medicare & Medicaid Services were the top three assets.

The assessment occurs every 3 years. CRIS has gone through two assessments. The first one resulted in a heat map that was entirely red (deficient). In response, the Department of Clinical Research Informatics modified the documentation to show every security control. The second assessment showed more green areas, but it was necessary to ensure that CRIS and its security boundary were separate from all other systems. That work is underway. In addition, the team had to modify the architecture in order to not have everything encrypted in transit, to allow the assessors to see the traffic that is going across.

Sunrise Clinical Manager is the commercial name of CRIS. (CRIS is the CC's name for the system.) The Sunrise product line has been controlled by three different companies (Eclipsys, Allscripts and Altera Digital Health). CRIS allows the CC team to build anything it wants, but the team has to be able to support what it builds. CRIS was installed in 2004 as the best available EHR solution for the clinical research environment. CRIS has to support the workflow of all 27 NIH ICs, for both inpatients and outpatients. Since 2022, the vendor has been Altera Digital Health. Since the CC's focus is on clinical research, most solutions that work in the commercial world do not have the flexibility needed, and they do not all cover clinical research.

The CC team has adopted and utilized its EHR system effectively. There is very little paper; there is no medical records room, only a small set of shelves for the few documents that are

awaiting scanning. Documents are scanned on the hospital floors. For Allscripts, the CC was certified and recertified at Stage 7—the only federal entity to achieve this status.

Dr. McKeeby explained that the CC is exempt from the Health Insurance Portability and Accountability Act (HIPAA). The CC and CRIS follow the Privacy Act of 1974. It is important to avoid turning the HIPAA switch, regardless of what EHR system is used. The CC almost entered that territory some years ago, when there was a plan to start third-party billing for radiology, but that idea was abandoned.

Dr. McKeeby said that the CRIS EHR system is now 19 years old, has become complex and fragile, and is reaching the end of its useful life. The CC will be migrated to version 22 in the spring. There are also issues of user acceptance and the risk that an outdated system could affect staff morale.

Dr. McKeeby said that it is time to review other options for EHR systems in terms of a business case. Work has begun on the procurement component.

***Limitations of CRIS***

Dr. McKeeby presented a "flower diagram" representing the current system, including the CRIS boundary, the vendor product, and Biomedical Translational Research Information System (BTRIS), which feeds into the ICs' systems. FollowMyHealth is the bolt-on patient portal.

During the early years of the COVID-19 pandemic, the system needed to be modified to add employee testing and vaccinations. Dr. McKeeby's team accomplished this task in just 3 weeks, thanks to the hard work of an excellent group and the flexibilities of CRIS. However, sustaining that level of effort and flexibility is challenging.

Academic organizations, such as Johns Hopkins University, the Mayo Clinic, and Vanderbilt University had many separate systems, so they were able to get rid of all of them when they went to centralized systems. The CC's go-live for a new system would be more complicated, since everything was built in CRIS without any extra systems.

Dr. McKeeby discussed system downs that result from security requirements and software updates. When both scheduled and unscheduled downs are accounted for, the system's uptime is 98.52%, which may sound good, but to a user or patient trying to access the system, it is an inconvenience. This is not a number to be proud of.

Dr. McKeeby identified the top six issues with CRIS:

- Lack of seamless integration across departments (i.e., Laboratory, Radiology, Medication, Transfusion Medicine, and Perioperative Clinical Information Systems)
- Lack of an encounter-based visit model, which poses limitations for management of ambulatory visits, integration to clinical systems, and synchronization to a protocol pathway
- Patient engagement modules (e.g., FollowMyHealth patient portal) that are not intuitive or easy for patients or clinicians to use
- Documentation and flowsheets that are not built using standard documentation terminology, scales (e.g., pain scales), advanced tools to populate documentation, and navigation tools, making it difficult to make clinical decisions

- Workflows that are not built into or utilized in CRIS, leaving clinicians to develop their own workflows for patient care
- Inability to sustain custom development, given the limitations of the current system

Dr. McKeeby said that the annual CRIS survey shows that user satisfaction has fallen over time.

***Proposed EHR System Requirements***

Dr. McKeeby spoke about the need for a system that is monolithic and integrated that can support direct patient care, administrative functions, and research functions (i.e., clinical research workflows and clinical research data/terminology). A component comparable to BTRIS will still be needed as a bridge between the CC and the ICs' research data systems.

This is a complex organization-wide project with IT components. It is not an IT project. The project will require everyone's participation, since it will migrate external clinical information systems into an integrated EHR system.

According to Dr. McKeeby, these are the top six desired outcomes for a new system:

- Streamlined patient throughput and clinical workflow to provide the patient story concisely (i.e., clinicians should be able to understand a patient's story before entering their room)
- Improved patient safety and clinical care delivery quality
- Improved patient experience and engagement.
- Better decision making across clinical care roles within the CC
- Reduced complexity to support systems from security patching, configuration, and customization
- Better system availability

If NIH and HHS cannot find funding, and we keep "kicking the can down the road," key improvements cannot keep being deferred:

- Implementation of encounter-based visits
- Improved usability
- Improved physician and nursing documentation
- Implementation of interoperability mechanisms to and from external organizations
- Precision medicine clinical decision support

***Progress to Date and Next Steps***

Dr. McKeeby said that Deloitte built the original business case for a new EHR system in 2019. MITRE is currently working on the procurement, which will be by open bidding. Currently, MITRE is creating the performance work statement (PWS) and the statement of work (SOW).

MITRE has collected input from more than 30 focus groups. Job shadowing and interviews with CC and IC leaders were also carried out.

In all, more than 1,000 individual requirements have been identified.

The main challenge, according to Dr. McKeeby, is securing the funding for the project. The CC is reviewing funding options with the HHS and NIH. An initial request for $150 million was

submitted as a Nonrecurring Expenses Fund (NEF) request. NIH approved the Federal Information Technology Acquisition Reform Act/Information Technology Acquisition Review.

In terms of next steps, Dr. McKeeby said that MITRE is continuing to work on the PWS/SOW and is facilitating clinical workflow modeling. Once funding is secured, the PWS/SOW can be submitted.

***Discussion***

- Mr. Baum compared the robust requirements for the CC's EHRs to those for a satellite program.
- Dr. Chin asked about the meaning of "HIPAA exempt." Dr. McKeeby said that the CC is not a "business associate" as defined in HIPAA, and no data from CC patients are sent to payers, since the CC does not do any billing. He said that in the future, it might be necessary to change the HIPAA condition if any data were to start flowing out from medical records. Dr. Gilman clarified that the CC is bound by the Privacy Rule of 1974 for protected health information; the CC is HIPAA observant though not HIPAA compliant.
- Dr. Chin said that Dr. McKeeby presented a very convincing case about how complex the system is. Considering the system's complexity, a cost of $150 million seems low. Academic centers spend a great deal more on their IT infrastructure. Dr. McKeeby said that the $150 million represents ownership value as identified by MITRE, but the CC still needs to validate that number. He also clarified that the amount for the first 5 years is $150 million. Industry will tell NIH what the cost will be through the acquisition process.
- Dr. Samitt applauded Dr. McKeeby's statement that this is not an IT endeavor and that many people need to be involved. He asked Dr. McKeeby about his degree of confidence that an EHR system exists that can meet all the requirements. For example, do commercial systems allow the degree of flexibility that was needed during the COVID-19 pandemic? Dr. McKeeby said that one requirement will be that the system be agile. The team needs to identify requirements for agile development. Also, academic centers have shown that a commercial EHR system is feasible for clinical and research uses. He believes that it is more likely than not that some commercial product could support all of the CC's needs.
- Mr. Leslie asked how the performance and satisfaction scores compare against other major hospital centers. Dr. Reel said that she could not offer a good comparator based on her experience with Johns Hopkins University, but the vendor community has an advantage when it comes to user satisfaction metrics because of their access to shadow systems that kick in when downs occur. Because of the shadow systems, users do not "see" the system down. Dr. McKeeby said that the CC has sufficient system redundancy to handle critical functions, such as printing labels on the floor, during a down. He mentioned efforts to get benchmarks in place for user satisfaction, but those efforts have not succeeded yet. For each vendor, user satisfaction scores are based on surveys, although the surveys tend to have low response rates. Dr. Reel said that satisfaction scores at Johns Hopkins refer to the whole toolset.

- Ms. Royster complimented Dr. McKeeby for all he and his team do and for explaining the CC's HIPAA exemption. Dr. McKeeby said that the team is talented and hardworking. They are "in it to win it, sometimes working 80 hours per week."
- As a patient advocate, Mr. Baum pointed out that patient focus groups, including the NIH Patient Advisory Group (PAG), offered input, although this contribution was not shown on the slide about focus groups. Dr. McKeeby thanked Mr. Baum for the reminder and acknowledged the PAG's feedback.

## Wellness Initiative at the NIH Clinical Center

*Ann Berger, M.D., M.S.N., Chief, Pain and Palliative Care Service, NIH Clinical Center; and John M. Pollack, M.Div., BCC, Chief, Spiritual Care Department, NIH Clinical Center*

Dr. Berger explained that the Clinical Center's Wellness Initiative aligns with the Surgeon General's framework for workplace mental health and well-being. The framework has five essential elements:

- Protection from harm
- Connection and community
- Work-life harmony
- The feeling that one matters at work
- Opportunity for growth

Dr. Berger said that all five elements center around the worker voice and equity. The Substance Abuse and Mental Health Services Administration (SAMHSA) is also committed to the area of mental health and well-being. SAMHSA's wellness model consists of spiritual, intellectual, physical, environmental, financial, occupational, social, and emotional dimensions. The model involves the whole workplace and the whole person, and it also encompasses resilience.

The National Academy of Medicine (NAM) has also convened workshops and collaborative groups on the topic of medical staff wellness. NAM has found substantial symptoms of burnout among the U.S. clinical workforce, including 35% to 54% of nurses and physicians and 45% to 60% of medical students and residents.

Dr. Berger identified some key factors that affect employee wellness or burnout:

- Workload and job demands
- Efficiency and resources
- Meaningfulness of work
- Organizational culture and values
- Social support and community at work
- Work-life integration
- Control and flexibility

When these factors are optimal, the result is greater engagement, vigor, dedication, and absorption; when they are not, the outcomes can be burnout, exhaustion, cynicism, and inefficacy. Dr. Berger explained that the Mayo Clinic had contributed much of this research and has developed a survey for workers in the workplace. The CC plans to implement the survey.

### *Culture of Wellness in the Clinical Center*

Dr. Berger listed some benefits of a culture of wellness that were articulated during discussions with Dr. Gilman about 2 years ago:

- **Benefits to the CC when stress and burnout are decreased:** Lower staff turnover, reduced costs to recruit and retain staff, increased patient satisfaction, fewer medical errors, less need for disciplinary action, and improved work environment.
- **Benefits for CC staff from the loading dock to the bedside to the C-suite:** Decreased stress and burnout; increased compassion and empathy; optimized physical, mental, and spiritual health; allowing staff to reconnect with the joy and meaning of their work.
- **Benefits for NIH:** Enhanced focus on the NIH mission and, more specifically, on the CC as a house of hope, channeling a sense of meaning and purpose throughout the organization.

The goal of the initiative is to establish a wellness program that suffuses throughout the organization, from the loading dock to the C-suite. The spiritual piece is an important component for decreasing stress and burnout.

### *Nuts and Bolts of the CC Wellness Initiative*

Mr. Pollack addressed some steps and metrics needed to implement a wellness program that would promote a culture of wellness within the CC. Needs include an overview of existing wellness programs, approval for new CC wellness programs, new strategies to improve wellness in the CC, and efforts to ensure inclusion of the entire CC workforce. In addition, Mr. Pollack said that the CC always does a good job of supporting staff during a crisis, but efforts are needed to find ways to *prevent* burnout and stress during crises. The general approach is to identify existing programs that work and expand them to other areas of the CC.

In terms of existing models of wellness, Mr. Pollack described peer-to-peer support available in the CC. This started as a program for bereaved staff when patients die, but peer-to-peer support is helpful for multiple types of events. For example, a few months ago, a staff member had a great tragedy occur outside of work. Within 30 minutes, a team responded to the unit. Also, in the CC's hospice unit, staff felt depleted after a number of long-term patients died. A team responded quickly to support and provide respite for the affected staff. The wellness program is building on these peer-to-peer efforts and embedding peer champions in units for early warning of crises and for identifying wellness resources.

Mr. Pollack offered other examples of support available through the wellness program:

- The CCND has a respite room. Between April and September 2023, there were 196 encounters.
- Morale is an important component of any wellness program. The CC's Materials Management and Environmental Services department reported 80 encounters during the period between April and September that provided opportunities for staff to step aside and celebrate their work.
- The Department of Clinical Research Informatics (DCRI) offers virtual relaxation sessions, which include chair yoga and music. A total of 529 encounters occurred

between April and September. This was an existing program that has been broadened to make it available to other CC staff.

- The Good Grief and Chocolate program helps staff work through the deaths of pediatric patients; 63 encounters took place during the period from April to September. Collaborators include the CCND, the 1NW unit of the CC, the Pediatric Clinic, the Children's Inn, DCRI, and the National Cancer Institute.

Mr. Pollack announced the launch of a Clinical Center Wellness Initiative web page on the CC Intranet to serve as a clearinghouse for wellness programs offered to CC staff, links to resources available to the wider NIH community, as well as self-help resources, and articles. It received 590 pageviews between April and September with minimal publicity as the focus now is on making the site more robust before more intensive promotion efforts.

***Discussion***

- Dr. Coots pointed out that weekend and evening shift personnel are harder to reach. Does the CC have care carts with snacks for staff who work those shifts? Dr. Jordan said that the CCND is working on a care cart. Code Lavender is available for individuals or units that are in distress.
- Ms. Royster said that she, as an NIH patient, was grateful for bedside visits from service animals, the support of staff, and use of the respite chair. She was glad to hear that such services have been extended to staff.
- Dr. Coots expressed his support for the CC's staff wellness efforts, noting that health care work is not getting any less stressful.

## Center for Alzheimer's and Related Dementias (CARD)

*Andrew B. Singleton, Ph.D., Director, Center for Alzheimer's and Related Dementias (CARD), NIA*

Dr. Singleton said that CARD is an initiative of NIA and the National Institute of Neurological Disorders and Stroke (NINDS). CARD is a highly collaborative endeavor; CARD investigators are already working with four or five other ICs on the basic science side and on clinical research studies. He presented CARD's unique structure and sources of support.

The idea for an intramural program devoted to Alzheimer's disease (AD) and Alzheimer's disease–related dementias (ADRD) came about during the winter holidays of 2018. There had been growing emphasis on dementias, supported by large increases in funding. The intramural research program seemed to offer special opportunities that would drive progress. For example, intramural investigators do not have to be concerned about grant cycles; they can start working on ideas as they surface. The intramural program has stable, generous resources. Rather than measuring success on the basis of publications, tangible progress toward a final goal is the metric for a successful intramural project. With these structural opportunities come structural responsibilities, such as the ability to take on critical projects that others cannot easily address. The intramural program can focus on complementing current research activities by closing resource and research gaps—for example, by providing a platform, resource, or data needed to propel progress.

Dr. Singleton said that CARD was created with a clear mission: "Initiate, stimulate, accelerate, and support research in AD/ADRD, leading to the development of improved treatments and preventions for these diseases." CARD can take on a primary or a collaborative role in research projects, and it can prioritize projects that require a high tolerance of failure.

The following are the scientific priorities that CARD is currently focusing on:

- Molecular pathogenesis anchored in genetics
- Disease subtyping, risk prediction, and disease progression
- De-risking of AD/ADRD therapeutic approaches
- Development and application of precision therapeutics

Anyone can go to the CARD website and propose a research challenge. Potential projects are assessed in terms of their fit with the mission and whether CARD is the right entity to carry out the project. Dr. Singleton said that some CARD investigators hold positions in other ICs but come to work on certain projects at CARD. Anyone can come and contribute to CARD. Each project is run by a project management group that checks progress every 6 months.

CARD occupies a new 25,000-square-foot building. About half of the building is laboratory space, and about half of the remaining space is desks and open offices. Some offices are bookable, and others are permanent. The idea is that people can come and go rather freely.

***CARD Basic and Early Translational Program***

For CARD's basic and early translational research projects, the roster of researchers includes term-limited early-stage investigators, tenure-track investigators, and visiting investigators from the intramural program, academia, and industry. Most projects are run by outside investigators. Various groups of experts in topics such as advanced analytics, genetics, and single-cell sequencing technologies support CARD projects. Dr. Singleton offered a list of examples of CARD projects in the Basic and Early Translational Program:

- Single-Cell Brain Atlas—using ancestrally diverse samples and data from the North American Brain Expression Consortium and Human Brain Collection Core
- Aging Cellular Systems via Epigenetics
- Modeling Cellular Senescence
- A Pathway to Dissect Bioactivity of Variants of Uncertain Significance
- Induced Pluripotent Stem Cells Neurodegenerative Disease Initiative (iNDI)
- Multi-Partner Consortium to Expand Dementia Research in Latin America
- The Reasons for Geographic and Racial Differences in Stroke—Dementia Component
- Viral Exposure and Risk for Neurodegenerative Disease
- Long-Read DNA Sequencing, Discovery, and Resource Production
- TDP-43 Biomarker Project
- AutoTAC Therapeutic Strategy for Removing *tau*

***CARD Clinical Translational Research Program***

Dr. Singleton said that the aim of the clinical program is to enable precision medicine (i.e., "Right patient, right therapeutic, right time"). In the area of precision therapeutics, Dr. Singleton said that high-confidence precision therapeutic targets exist and that genomic therapies (e.g.,

CRISPR) are effective, and regulatory pathways are becoming clearer for antisense oligonucleotide (ASO) therapy. The intramural research program is well suited to taking on such projects because of the availability of clinic and hospital infrastructure, experience in genomic medicine, and funding availability at the front end to provide speed and equity.

Three arms comprise the CARD Clinical Translational Research Program:

- Natural history studies involve deep phenotyping of AD/ADRD patients.
- Translational studies aim to develop and de-risk precision therapies.
- Clinical trials involve the application of precision therapies, such as ASOs, CRISPR, and novel small molecules, including TDP-43 de-aggregates.

On the clinical translation side, Dr. Singleton said that CARD also intends to conduct challenge projects (e.g., CRISPR/Cas9 therapy, pathogenicity of variants of unknown significance, use of wearables and other digital health and sensing technologies).

By building synergy with other projects within CARD and the intramural program generally, coupled with biomarker development and data science and a culture of rigor, collaboration, and transparency, Dr. Singleton envisions the CC becoming the destination medical center for precision trials in AD/ADRD. CARD worked with the CC to identify a 9,000-square-foot space for clinical trials.

The next step is to find a director for the Clinical Translational Research Program at CARD. This leader would need to be someone with a proven record in the AD/ADRD space, who recognizes the potential of the Intramural Research Program, and is a clinician-scientist with a clear vision and the skill necessary to implement the vision for CARD.

***Discussion***

- Dr. Coots remarked that CARD seems similar to the Advanced Research Projects Agency for Health in many respects. He asked whether CARD also fosters a sense of urgency and speed and, if so, how CARD leaders ensure that others share that sense of urgency. Dr. Singleton said that some people advised him to try to get some quick wins, but he has resisted that approach. CARD operates with a sense of speed and urgency but also maintains an absolute focus on its mission and milestones, as well as NIA's mission. When evaluating a proposed project, Dr. Singleton said he asks questions such as, "Why CARD?" and, "Is there someone who could do it better?"
- Dr. Coots said that the Board looks forward to hearing updates on CARD at future meetings.

## Adjournment

Dr. Coots called for new business; hearing none, he thanked the presenters and adjourned the meeting at 12:57 p.m.

/ Norvell Coots /

Norvell Coots, M.D.
Chair, NIH Clinical Center Research Hospital Board
President and CEO, Holy Cross Health

/ Tara Schwetz /

Tara Schwetz, Ph.D.
Executive Secretary, NIH Clinical Center Research Hospital Board
Acting Principal Deputy Director, NIH

## Abbreviations and Acronyms

| | |
|---|---|
| ADC | average daily census |
| AD/ADRD | Alzheimer's disease/Alzheimer's disease–related dementias |
| AHRQ | Agency for Healthcare Research and Quality |
| ANCC | American Nurses Credentialing Center |
| ASO | antisense oligonucleotide |
| BTRIS | Biomedical Translational Research Information System |
| CARD | Center for Alzheimer's and Related Dementias |
| CC | Clinical Center |
| CCRHB | Clinical Center Research Hospital Board |
| CEO | chief executive officer |
| CFS/ME | chronic fatigue syndrome/myalgic encephalomyelitis |
| CNO | Chief Nurse Officer |
| CRIS | Clinical Research Information System |
| DCRI | Department of Clinical Research Informatics |
| DEIA | diversity, equity, inclusion, and accessibility |
| EDI | (NIH) Office of Equity, Diversity, and Inclusion |
| EHR | electronic health record |
| FEVS | Federal Employee Viewpoint Survey |
| FTCA | Federal Tort Claims Act |
| HHS | U.S. Department of Health and Human Services |

| | |
|---|---|
| HIPAA | Health Insurance Portability and Accountability Act |
| ICs | Institutes and Centers |
| IT | information technology |
| NAM | National Academy of Medicine |
| NEF | Nonrecurring Expenses Fund |
| NIA | National Institute on Aging |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIH | National Institutes of Health |
| NINDS | National Institute of Neurological Disorders and Stroke |
| NLM | National Library of Medicine |
| PASC | post-acute sequelae of COVID-19 |
| PAG | Patient Advisory Group |
| PWS | performance work statement |
| RECOVER | Researching COVID to Enhance Recovery |
| RFI | request for information |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SOW | statement of work |
| SRLM | Surgery, Radiology, and Laboratory Medicine (wing) |