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Twenty-Fourth Meeting of the Clinical Center Research Hospital Board

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Contents

Clinical Center Research Hospital Board iii

Executive Summary 1

Welcome and Board Chair's Overview 3

NIH Director's Remarks 3

- NIH Leadership Changes 3
- NIH Budget Update 4
- Staff Awards 4
- 70th Anniversary of the CC 5
- COVID-19 Updates 5
- Discussion 5

NIH Clinical Center (CC) CEO Update 6

- Special Events 6
- Groundbreaking for the CC Surgery, Radiology, and Laboratory Medicine (SRLM) Wing 6
- CC Leadership Changes 6
- CC Staff Honors 6
- Hospital Census 7
- Diversity, Equity, Inclusion, and Accessibility (DEIA) Updates 7
- Health Disparities 7
- COVID-19 8
- Preparing for the Joint Commission Survey 8
- Clinical and Safety Performance Metrics 8
- Closing 8
- Discussion 8

Before Strategic Planning Comes Strategic Thinking (Structured Brainstorming) 9

- Guiding Principles 9

Building on the Four Broad Aims of the 2019 Strategic Plan ... 10
Expanding Pediatric Research in the CC ... 11
Pharmaceutical Development Service (PDS) ... 11
Discussion ... 12

Translational Biobehavioral and Health Disparities Branch (TBHD):
From Community to Bench and Back ... 12

What Is Next for TBHD? ... 13
Discussion ... 13

Clinical Center Leadership Development ... 14

CC Leadership Development Programs ... 14
NIH Leadership Programs ... 15
Individual Development Plans (IDPs) ... 15
Conclusion ... 15
Discussion ... 15

ARPA-H: The Mission ... 16

Overview of ARPA-H ... 16
Attributes of ARPA-H ... 16
Program Development and Mission ... 17
Discussion ... 18

Closing Remarks ... 19

Adjournment ... 19

Abbreviations and Acronyms ... 21

Clinical Center Research Hospital Board

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

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

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Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 24th meeting in person and via videoconference on June 16, 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 9:30 a.m. ET. He welcomed everyone to the meeting and indicated who was attending in person and who was attending virtually. Dr. Coots noted that the meeting started later than usual because new Board members had toured the Clinical Center beforehand.

Lawrence A. Tabak, D.D.S., Ph.D., Acting Director of NIH and Executive Director of the CCRHB, and James K. Gilman, M.D., CEO of the NIH Clinical Center (CC), both highlighted upcoming events for the CC's 70th anniversary. Dr. Tabak also highlighted changes in NIH leadership and commented on 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.

Dr. Tabak presented key aspects of the fiscal year (FY) 2023 budget, which included funding for the Advanced Research Projects Agency for Health (ARPA-H) as an independent entity within NIH. The budget represents a 6.5% increase over FY 2022; however, Congress did not pass the administration's pandemic preparedness proposal or provide additional COVID-19 funds.

Dr. Tabak also highlighted certain NIH-funded accomplishments in the fight against the COVID-19 pandemic, although long COVID continues to impose a heavy burden.

Dr. Gilman highlighted an art installation in the CC's Healing Garden featuring statues of women innovators in science, technology, engineering, and medicine. The groundbreaking ceremony for the CC Surgery, Radiology, and Laboratory Medicine (SRLM) wing took place on May 16, 2023, and featured a keynote by U.S. Department of Health and Human Services (HHS) Deputy Secretary Andrea Palm, M.S.W., and speeches by NIH leaders. He also announced the names of CC staff who have received honors recently.

Dr. Gilman reported that the inpatient census is up 12% over 2022, but the average length of stay is down by 12%. The number of outpatient visits increased 11%, with the number of new patients up 12%.

The Clinical Center remains highly committed to diversity, equity, inclusion, and accessibility (DEIA), an important focus of the *NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA)* for FY 2023–2027. NIH stood up the DEIA Advisory Committee in January 2023 and established DEIA Advisory Committee subgroups in March. The CC's DEIA programs also launched in March.

Dr. Gilman spoke about preparing for the CC's 2024 strategic plan, noting that the 2019 strategic plan was the first of its kind for the CC. In his presentation, Dr. Gilman focused on three of the CC's seven guiding principles that need to be updated, as well as changes to the CC's broad aims, including a possible new strategic aim to improve access and use of information of all

types on the NIH website. Procuring a new electronic health record system or improving the existing one might also be necessary.

Dr. Gilman explained that earlier this year, the CCRHB received and voted to accept the report of the CCRHB Children's Working Group (CWG) on possibly increasing the number of children cared for at the CC Research Hospital while lowering the age for pediatric participation in intramural trials from 3 years to 6 months, with patient safety being of paramount importance. Although budget restrictions mean that it might not be possible to implement the CWG's recommendations in the near term, the CC is taking steps to facilitate more pediatric research in the center.

Gwenyth R. Wallen, Ph.D., RN, Chief, Translational Biobehavioral and Health Disparities Branch (TBHD), and CC Senior Investigator, introduced the branch to the CCRHB. She outlined TBHD's mission, vision, and goals and highlighted several TBHD projects that cover the spectrum of biobehavioral research.

Charlotte Pak, M.A., Chief, Office of Workforce Management and Development (OWMD), NIH CC, addressed a question raised by the CCRHB during its last meeting about programs to develop internal candidates for leadership roles. She described internal and external leadership development opportunities for CC staff. Interest and participation in these programs have grown significantly over last few years, partly because of increased communication regarding opportunities and support from senior leadership. In addition, Ms. Pak said that leadership development is a key component of the CC's strategic plan.

Jennifer Roberts, Ph.D., Director, Resilient Systems Office, ARPA-H, spoke about ways that the CC could support the work of this new agency, which aims to identify areas where technical breakthroughs in the commercial world could accelerate better health outcomes for everyone by closing gaps and moving developments from the laboratory to the real world.

Dr. Coots announced that the next meeting would be on October 20, 2023. The 2024 schedule is forthcoming. He adjourned the meeting at 12:47 p.m.

Meeting Summary
February 17, 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 to the meeting, which was conducted in a hybrid format. He announced that the later starting time (9:30 a.m.) was chosen as new Board members toured the Clinical Center before the meeting. He also noted that some CCRHB members, as well as James K. Gilman, M.D., Chief Executive Officer of the NIH Clinical Center, would be participating remotely.

Dr. Coots welcomed Sherin U. Devaskar, M.D., and Jack Leslie as the newest full members of the CCRHB, bringing the roster up to 11 people. Dr. Coots also welcomed NIH leaders, members of the NIH community, and members of the public who joined the livestreamed meeting.

In addition to Dr. Coots, the following Board members attended the meeting in person: David M. Baum, PMP; David C. Chin, M.D., M.B.A.; Julie A. Freischlag, M.D.; and Antoinette Royster. Attending virtually were Board members Regina S. Cunningham, Ph.D., RN, FAAN; Sherin U. Devaskar, M.D.; Steven I. Goldstein, M.H.A.; Jack Leslie; Stephanie Reel, M.B.A.; and Craig E. Samitt, M.D., M.B.A.

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 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 (NCI). Dr. Tabak outlined the nomination and confirmation process. The Senate must confirm the nomination before Dr. Bertagnolli can assume leadership of NIH. Until then, Dr. Tabak will continue as Acting Director.
- Lauren Higgins is serving as the Acting Associate Director for Legislative Policy and Analysis while the search for a permanent director is ongoing.
- Bill G. Kapogiannis, M.D., is the Acting Associate Director of the Office of AIDS Research (OAR). A search is underway for a new director to replace Maureen Goodenow, Ph.D., as the Director of OAR.
- Stefan M. Pasiakos, Ph.D., FACSM, is coming on board in July 2023 as the Director of the Office of Dietary Supplements. Dr. Tabak thanked David Murray, Ph.D., who has been serving as Acting Director.

- Wendy B. Smith, Ph.D., is now the Acting Associate Director for the Office of Behavioral and Social Sciences Research.
- The new Director of the NIH Tribal Health Research Office is Karina L Walters, Ph.D., M.S.W. Dr. Tabak explained some of the complexities that come with engaging American Indian Tribes, which are sovereign nations. Dr. Walters is an enrolled member of the Choctaw Nation of Oklahoma.

NIH Budget Update

Dr. Tabak explained that the agency's budget is presently in a very fluid state. For fiscal year (FY) 2023, Congress provided NIH with the full-year discretionary appropriation and authorized funding for the Advanced Research Projects Agency for Health (ARPA-H) as an independent entity within NIH. However, Congress did not pass the administration's pandemic preparedness proposal or provide additional COVID-19 funds.

Dr. Tabak presented highlights of the FY 2023 budget. Congress increased NIH's budget by $3 billion (6.5%) compared to 2022. The FY 2023 budget of $49.2 billion includes $1.5 billion in funding for ARPA-H. The largest targeted increase was for Alzheimer's disease, followed by an NCI grants supplement, HIV/AIDS research, buildings and facilities, the NIH Common Fund, the *Brain Research Through Advancing Innovative Neurotechnologies*® (BRAIN) Initiative, health disparities, the Accelerating Access to Critical Therapies for ALS (amyotrophic lateral sclerosis, or Lou Gehrig's disease) Act, and opioid/pain research. Dr. Tabak said that the agency is grateful to Congress for the additional resources.

NIH is continuing critical COVID-19 research and resources using supplemental appropriations for NIH, as well as amounts provided by the U.S. Department of Health and Human Services (HHS) and administered under delegated authority. This support includes the new Project NextGen.

The Fiscal Responsibility Act of 2023 (FRA) calls for holding nondefense spending roughly flat in FY 2024 and then increasing spending by 1% in FY 2025. The FRA increases the federal debt limit, establishes new discretionary spending limits, rescinds unobligated funds, expands work requirements for federal assistance programs, and modifies other requirements related to the federal budget process. The FRA is an incentive for agencies to spend unobligated funds to avoid rescission. Dr. Tabak said that NIH staff worked very hard to ensure that resources were spent in appropriate ways, but certain COVID-19 monies were rescinded. The President's budget for 2024 will have to comport with the FRA. NIH will continue to make the case to Congress about the importance of disease research.

Staff Awards

Dr. Tabak announced that an interdisciplinary group from the National Human Genome Research Institute is among the finalists for the 2023 Service to America Awards. The team led an effort in telomere-to-telomere genome sequencing that required significant computational power.

Eric J "Rocky" Feuer, Ph.D., of NCI, is a finalist for the Paul A. Volcker Career Achievement Award. He used data and statistical analysis to help stakeholders understand the impact of cancer on the U.S. population. This work supports the Cancer Moonshot℠.

Dr. Tabak said that the agency was honored by a visit from HHS Deputy Secretary Andrea Palm, M.S.W., who attended the groundbreaking event for the CC Surgery, Radiology, and Laboratory Medicine (SRLM) wing and also learned about NIH efforts in mental health. She met with Nora Volkow, M.D.; Diana Bianchi, M.D.; and Griffin Rodgers, M.D., and was introduced to a person who has dealt with clinical depression throughout their life.

70th Anniversary of the CC

Dr. Tabak announced several upcoming events to celebrate the CC's milestone anniversary. Grand Rounds on June 28, 2023, will feature a presentation by former NIH Director Francis Collins, M.D., Ph.D. The "70 Years of Firsts" event will take place sometime this year, although the exact date or dates have not yet been announced.

COVID-19 Updates

Dr. Tabak said that NIH continues to shine a light on long COVID through RECOVER (Researching COVID to Enhance Recovery), the world's largest enrolling clinical study of long COVID.

Dr. Tabak noted that SARS-CoV-2 continues to evolve. The ancestral strain is very different from the current dominant strain (omicron). In essence, we are dealing with many different viruses, although the original strain is linked with the most profound sequelae. Nearly every organ system is affected by the disease, something that is unprecedented among viral diseases. There appear to be different types of long COVID, with some being more neurologic and others more neuromuscular or cardiac in terms of affected body systems.

NIH research is also investigating links between and similarities of long COVID with other diseases, such as myalgic encephalomyelitis/chronic fatigue syndrome. Studying long COVID in that context could provide important insights. Treatments for long COVID are also being investigated.

According to Dr. Tabak, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is continuing a series of clinical trials testing novel and repurposed drugs for treating COVID-19. The ACTIV network has enrolled more than 23,000 patients at 312 sites. Dr. Tabak said that ACTIV research led to development of six effective treatments and also ruled out more than 700 agents that were ineffective.

Discussion

Dr. Coots noted that at Holy Cross Health, clinicians are finding that most cases of long COVID result from infections caused by the original strain of SARS-CoV-2 rather than variants, including the Omicron strain.

NIH Clinical Center (CC) CEO Update

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

Special Events

Dr. Gilman presented the logo design for the CC's 70th anniversary. In addition, the Foundation for Advanced Education in the Sciences created a special anniversary challenge coin that will be available in the NIH bookstore. A virtual anniversary background for Zoom and Microsoft Teams meetings is also available.

Dr. Gilman showed photos of an art installation in the CC's Healing Garden that consists of 10 life-sized 3D-printed orange statues of women innovators in science, technology, engineering, and medicine. The principal collaborator for the installation was the #IfThenSheCan exhibit, which includes 120 such statues, each with a QR code that allows viewers to access the women's stories. The exhibit highlights how a more diverse, more inclusive workforce will strengthen the world's shared future.

Groundbreaking for the CC Surgery, Radiology, and Laboratory Medicine (SRLM) Wing

The groundbreaking ceremony for the SRLM wing occurred on May 16, 2023, and featured a keynote address by Deputy Secretary Palm, as well as speeches by various NIH leaders, including Drs. Tabak and Gilman, Daniel Wheeland, and Steven Rosenberg, M.D., Ph.D.

Dr. Gilman announced that Richard Bond will be serving as the SRLM Project Executive under a special agreement with the Uniformed Services University of the Health Sciences (USUHS) that will allow Mr. Bond to retain his position there as Special Assistant to the President for Strategic Infrastructure Initiatives while providing temporary support to the CC a few days per week.

CC Leadership Changes

Dr. Gilman said that he will soon be able to announce the name of the next Chief Nurse Officer. Other vacancies include the Chief of the Pharmacy Department, Chief of the Department of Transfusion Medicine, and CC Executive Officer. Daniel Lonnerdal, M.S., FACHE, who served as the CC Executive Officer for 4 years, has left the position. Ila Anita Flannigan, M.H.S.A., FACHE, will step in as the Acting Executive Officer, and David Saeger, M.P.A., will step up as Acting Deputy Executive Officer. Dr. Gilman welcomed Sunil Vasudevan, M.E., M.S., as the new CC Chief Financial Officer.

As announced at the last CCRHB meeting, John Gallin, M.D., retired in late March, leaving vacancies for both of his CC roles. Dr. Gilman said that Leighton Chan, M.D., M.P.H., is now the CC's Acting Chief Scientific Officer.

CC Staff Honors

Dr. Gilman recalled that the CC CEO award honorees received virtual awards in December 2022. In-person distribution of awards, certificates, and letters occurred on May 2 this year; however, there was a problem with the certificates that required them to be reprinted. The corrected ones will be handed out soon.

Dr. Gilman congratulated Yukiko Asada, Ph.D., who is with the CC's Bioethics Department, on her selection as a 2023 NIH Distinguished Scholar. Her research focuses on ending health disparities and inequalities.

Three senior CC leaders participated in the CC Gingerbread House video. The video won in the Best Digital Media category, boosting contributions to the Combined Federal Campaign of the National Capital Area. The CC surpassed its $60,000 goal and ended up raising more than $101,000.

Hospital Census

Dr. Gilman reported that the inpatient census is similar to last year's: still below the 3-year average (FY 2019–FY 2021). Compared with 2022, admissions are up 12%, but the average length of stay is down by 12%. The number of outpatient visits is up 11% over last year, with the number of new patients up 12%. Since telehealth visits were initiated in April 2020, the number of visits has been fairly stable, between 500 and 600 per month.

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

The Clinical Center remains focused on DEIA—the focus of the *NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility (DEIA)* for FY 2023–2027. NIH stood up the DEIA Advisory Committee in January 2023 and established subgroups in March. The CC's DEIA programs launched in March as well.

Dr. Gilman said that NIH has convened three DEIA discussion forums* so far this year:

- A facilitated discussion on police brutality took place on March 21.
- A facilitated discussion on excessive use of force occurred on April 18.
- A presentation on sex, gender, pronouns, and more was offered on June 12. More than 350 people participated in the VideoCast event.

Dr. Gilman highlighted NIH's upcoming DEIA activities, which include operationalizing DEIA Advisory Committee subgroups, establishing DEIA awards and recognitions, and developing and implementing racial and ethnic equity plans (REEPs).

NIH is also recognizing national commemorations, including three for June: LGBTQ+ Pride Month, Caribbean American Heritage Month, and Juneteenth.

Health Disparities

Dr. Gilman announced that CC workgroups are in preliminary discussions to establish a health disparities program framework, focus, metrics, data collection, initiatives, and interventions. The Health Disparities Clinical Center Workgroup is focusing on CC-wide needs with attention to Joint Commission requirements in conjunction with groups addressing disparities-focused medical education requirements. Dr. Gilman said that an executive group will discuss ways to meet Joint Commission recommendations regarding health disparities.

* Linked VideoCasts are accessible to NIH only.

COVID-19

According to Dr. Gilman, the CC is gradually relaxing COVID-19 restrictions. The CC is discontinuing at-will COVID-19 testing, but testing is available through the Occupational Medicine Service. Effective on June 5, new mask requirements were put in place in the CC, making masks mandatory in patient care areas only. Mask use is optional in non–patient care areas. Mask requirements may change based on SARS-CoV-2 and other respiratory virus activity levels.

Preparing for the Joint Commission Survey

As part of the CC's preparation for the next Joint Commission survey (probably in about a year), leadership rounds involve three teams of two CC leaders visiting one or two clinical areas weekly. Also, consultant organization conducted two mock surveys. In addition, as Dr. Gilman explained, general discussions take place with staff on the CC's safety culture based on results of mock surveys, concerns and barriers identified, and performance improvement projects. Focused areas of emphasis include sterile instruments and medication management. Environment-of-care observations are also taking place.

Mock tracers are done every few weeks by the Office of Patient Safety and Clinical Quality (OPSCQ) and the CC Nursing Department, along with a multidisciplinary group. Each mock tracer focuses on one topic or area related to specific issues identified in Joint Commission resources. The goal of the tracers is to continuously assess CC readiness and enculturate the tracer process.

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 OPSCQ.

Closing

Dr. Gilman briefly reviewed the day's agenda. He also noted that during the last meeting, Regina S. Cunningham, Ph.D., RN, FAAN, had asked about leadership development and the Board had raised questions about ARPA-H. In answer to these requests, CC staff arranged presentations during today's meeting by Charlotte Pak, M.A., on staff development opportunities and another by Jennifer Roberts, Ph.D., on ARPA-H.

Discussion

Dr. Cunningham asked whether CCRHB members would be able to attend Dr. Collins's Grand Rounds via a virtual meeting platform, such as Zoom. Dr. Gilman investigated further and reported that the Grand Rounds event will be viewable outside of NIH at the following link: https://videocast.nih.gov/watch=49881.

Dr. Devaskar asked how the Clinical Center would set up the health disparities work. Dr. Gilman said that he is deciding who will be responsible for the effort. He recalled previous presentations to the Board about patient satisfaction surveys; the data from those surveys are analyzed by the limited degree of racial/ethnic categorized data. Those data typically do not show differences by race/ethnicity. When it comes to health disparities, the focus is generally on health outcomes, but

the Clinical Center's population size is small and limited by the types of research being conducted (i.e., small trials). Therefore, it is sometimes challenging to collect enough data to compare groups and distinguish differences. Colleen Hadigan, M.D., M.P.H., Chief Medical Officer and Clinical Director of the CC, spoke about the racial/ethnic data that have been collected across NIH's Institutes and Centers (ICs) and across diseases. Some analyses have been performed, but the CC lacks data on socioeconomic status (e.g., region of the country, income). However, the CC might have data to enable a deep dive on literacy.

Another participant asked about data from people who are screened for study participation. Dr. Gilman explained that screening is often conducted in a telephone conversation, not in person. There are some data available on people who contact the CC through the call center, but study inclusion/exclusion criteria come from investigators who are mainly conducting small, disease-centered studies of rare and refractory diseases. Getting good comparators will be a struggle, but the Joint Commission mainly wants to ensure that staff are looking into health disparities.

Ms. Royster asked about DEIA efforts pertaining to CC patients. Dr. Gilman explained that the focus of the CC's DEIA programs is on the internal workforce, and Cecelia C. Henry, M.S., RN, the CC's Scientific Diversity Advisor, confirmed that focus.

Mr. Baum observed that several presentations during this meeting have referred to DEIA. He said that in industry, the best way to implement such changes is to "bake it in, not bolt it on." There has to be an equal emphasis on structural and process changes. DEIA should be integrated into the normal course of business. Dr. Gilman responded that the CC is starting to bake DEIA into its plans and initiatives, but he acknowledged that it is necessary to start somewhere. Some of those initial integrations certainly appear to have DEIA bolted on, but the CC has also chosen initiatives that go deep into the organization and will result in change. Dr. Gilman said that changes will take time, but the hope is that CC initiatives will become enduring changes. Dr. Coots said that DEIA concepts are not widely taught in medical school, even though DEIA will lead to health equity.

Before Strategic Planning Comes Strategic Thinking (Structured Brainstorming)

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

Dr. Gilman spoke about preparing for the CC's 2024 strategic plan, noting that the 2019 strategic plan was the first of its kind for the CC. The plans cover a 3- to 5-year horizon. During a CCRHB meeting last year, Dr. Gilman reviewed progress on the 2024 strategic plan and indicated that most milestones are being met. The listening and learning process for the 2024 strategic plan officially began today (June 16, 2023).

Guiding Principles

Dr. Gilman reviewed the CC's mission statement ("We do pioneering clinical research to improve human health.") and seven guiding principles:

1. Individual and collective passion for high reliability
2. Diversity and inclusion of people and ideas
3. Compassion for our patients, their families, and one another

4. Innovation in both preventing and solving problems
5. Accountability for optimal use of resources
6. Excellence in clinical scientific discovery and application
7. Commitment to professional growth and development

In his presentation, Dr. Gilman focused on three of the seven guiding principles (numbers 2, 3, and 7) that need to be updated:

- ***Diversity and inclusion.*** The current version of the second guiding principle does not include accessibility or topics currently dominating the discussion around issues of justice and policing. In addition, both at NIH and nationwide, there is now much greater emphasis on diversity, equity, and inclusion than in 2019.
- ***Compassion.*** The third guiding principle includes compassion for patients and their families and for fellow employees. However, it fails to mention compassion for self. People need to be easier on themselves, and that need should be reflected in this guiding principle.
- ***Professional growth and development.*** Since the 2018 strategic plan was issued, CC leaders have expanded opportunities for staff, and they will continue to do so. (A subsequent presentation during this meeting covered professional development in greater detail.)

Building on the Four Broad Aims of the 2019 Strategic Plan

Dr. Gilman presented the four broad aims articulated in the 2019 plan:

1. Continuing to lead the world in conducting first-in-human clinical research while maintaining our focus on rare and refractory disease.
2. Increasing the use of the CC by the NIH Intramural Research Program while simultaneously elevating the CC's status as a national resource for the extramural community.
3. Demonstrating profound respect for our patients, whom we recognize as our full partners in the clinical research enterprise.
4. Partnering with the ICs to recruit, develop, and retain the next generation of great NIH clinical researchers and the CC staff who will support their efforts.

Dr. Gilman said that the first two aims will likely remain unchanged in the next iteration of the strategic plan. The third may require minor modification. He went into some detail on the fourth aim, which is more important yet more challenging today than in 2019. The CC has made strides in DEIA over the past 5 years, but challenges remain. Incorporating a greater emphasis on DEIA makes the task even more complex, but the CC must reflect the population it serves. Such issues are not unique to the CC; health care leaders across the nation face challenges with DEIA. CC leaders are discussing whether to incorporate a DEIA focus in this aim or whether DEIA should be covered separately.

Dr. Gilman also proposed a new strategic aim: improved ability to access and use information of all types. It is not always easy to find information on the NIH website; perhaps the site needs to

be organized in a different way, or a new NIH website might be needed. It might also be necessary to procure a new electronic health record system or improve the existing one.

Expanding Pediatric Research in the CC

Dr. Gilman explained that earlier this year, the CCRHB received the report of the CCRHB Children's Working Group (CWG) and voted to accept it. The CWG assessed the intramural Pediatric Planning Group's (PPG) report, "Pediatric Care at the NIH Clinical Center," which was released on April 29, 2022. The CWG focused on possibly increasing the number of children cared for at the CC Research Hospital while lowering the age for pediatric participation in intramural trials from 3 years to 6 months, with patient safety being of paramount importance.

In earlier communications with Dr. Gilman, CWG members Dr. Devaskar and Clifford Bogue, M.D., indicated that the PPG's proposal to conduct early-in-human pediatric studies using extramural partners was feasible, but significant barriers exist. Dr. Bogue suggested an alternative approach: conducting early-in-human work at extramural academic medical centers. Dr. Gilman said that, because of 2024 budget concerns, trying to to set up a pediatric intensive care unit in the CC would not be realistic. He therefore concluded that pediatrics will continue to be a focus at the CC, but this is not the year to expand pediatric admissions. Dr. Gilman outlined plans for enhancing pediatric studies in the CC:

- Formalize a pediatric department in the CC.
- Advance the model of care so that all pediatric patients are cared for by doctors and nurses with age-specific competencies.
- Assess the possibility of lowering the age limit for admission from age 3 years to 2.
- Add child life specialists.

Pharmaceutical Development Service (PDS)

Dr. Gilman reported that the CC is very close to finishing the last of the pharmacy facilities. The PDS was a source of great concern and was permanently closed. However, the PDS housed a number of capabilities that investigators miss. He said that CC leaders and staff are addressing the possibility of reestablishing some portion of PDS capabilities, with the stipulation that safety and compliance are the foremost considerations.

CC leaders and staff are looking at some very basic functions that the PDS provided to see whether any could be restored. For example, Dr. Gilman reported that 503a (single-patient) compounding never stopped, but bandwidth in the CC is limited. The CC is not currently doing any 503b (batch) compounding, but perhaps the CC should develop in-house capability for batch compounding or outsourcing the work. The latter would require a discussion of funding and payments for sterile or nonsterile production. Dr. Gilman does not envision any manufacturing in the CC in the foreseeable future.

Dr. Gilman plans to consult many internal and external experts about the PDS. He hopes that by year's end, the CC can start working on a solid plan with the idea that it would be published in 2024.

Discussion

Mr. Baum said he did not see patients identified as a stakeholder group in the strategic planning effort. Dr. Gilman said that this would be a topic to take up during the fall PAG meeting.

Dr. Chin asked whether telehealth would be covered in the new strategic plan and inquired about the differences in the ICs' use of telehealth. Dr. Gilman said that the variation has more to do with the relative size of the ICs' clinical programs than their acceptance of telehealth. Telehealth capabilities are centered in the CC and available to all ICs. NCI leads the list because it is by far the largest IC in terms of numbers of patients. Dr. Chin would be interested to see data on appropriate use of telehealth for CC patients. Dr. Gilman said that for the most part, the CC does not tell ICs how to care for their patients. Nevertheless, much has been learned during the CC's telehealth journey, so it may be possible to consider ways to integrate the topic into strategic planning.

Ms. Royster asked about the possibility of incorporating more opportunities for biospecimen collection for research participants who live far from the CC. Dr. Gilman said that this was a topic under discussion some time ago, but he has not heard anything for a while. He said he will check for an update and respond more fully to the Board when he knows more.

Translational Biobehavioral and Health Disparities Branch (TBHD): From Community to Bench and Back

Gwenyth R. Wallen, Ph.D., RN, Chief, TBHD, Senior Investigator, NIH Clinical Center

Dr. Wallen previously interacted with the CCRHB in her prior position as the CC's Chief Nurse Officer (CNO). She presented TBHD's mission, vision, goals, and objectives. The branch received a great deal of input over a 6-month period to develop the mission, which reads as follows: "Advance interdisciplinary translational science focused in biobehavioral, clinical, and community studies to improve whole person health." TBHD's vision is an important one: "A world where sustainable health-promoting behaviors improve the health of all local and global communities through a network of institutional, scientific, and community-engaged partnerships leading biobehavioral research." Dr. Wallen described TBHD's four goals:

1. ***Advance key biobehavioral research areas.*** An evaluation by the NIH Board of Scientific Counselors led TBHD to focus on biobehavioral health. A memorandum of understanding with the National Institute of Nursing Research provided lab space for TBHD research.
2. ***Develop innovative training approaches.*** This goal dovetails with the CC strategic plan's emphasis on DEIA. A postbaccalaureate cohort from Johns Hopkins University with the potential for earning advanced degrees will be recruited.
3. ***Build collaborations to complement and accelerate TBHD's Intramural research portfolio.*** TBHD intends to build collaborations internally and externally, including with the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Dental and Craniofacial Research (NIDCR), and the National Heart, Lung, and Blood Institute. TBHD has received some intramural funding support. A collaboration with Scottish group involved in bioinformatics and biosciences is being set up.

4. ***Support NIH's DEIA strategic goals.*** SDOH models developed by TBHD and Healthy People 2030, can guide research. TBHD is also cultivating a research and training environment that will allow all trainees and employees to thrive, the Branch intends to conduct and support research that is important and relevant to diverse populations.

Dr. Wallen highlighted several TBHD projects that cover the spectrum of research:

- Jennifer Barb, Ph.D., M.S., and Katherine Maki, Ph.D., M.S., CRNP, are working on the human microbiome in health and disease in bench research projects. Dr. Maki's project is focusing on the oral microbiome of people seeking treatment for alcohol use disorder. Dr. Maki is the Head of the Biobehavioral and Integrated metagenOMics (BIOM). Dr. Barb has been at NIH for 20 years; she is an informatician who is heading up the Data Analytics and Translational Science Unit. Her project aims to elucidate links between the oral and gut microbiome and alcohol use disorder and myalgic encephalomyelitis/chronic fatigue syndrome.
- Lena Lee, Ph.D., M.S., RN, is leading a clinical study on a stress reduction intervention using virtual reality (VR) technology. The aim is to reduce the burden of cancer and treatment on family caregivers. The intervention consists of 4 weeks of daily VR sessions consisting of 360-degree, high-definition nature videos with audio. Each session lasts 20 minutes.
- Nicole Farmer, M.D., is the principal investigator for a clinical study investigating a biobehavioral approach to diet-related health disparities in patients and vulnerable populations. To support participation by people in rural areas, TBHD was able to secure funding through the National Human Genome Research Institute to allow blood draws to be done locally. Participants may then have a telehealth visit or come to the CC. So far, more study volunteers are participating off-site than on-site.
- Dr. Wallen explained that she is leading a study in the community that is examining health behaviors and chronic care management in diverse and vulnerable populations.

What Is Next for TBHD?

Dr. Wallen said that work is under way to build microbiome salivary science capabilities and set up capability for mobile electroencephalograms (EEGs).

Dr. Wallen thanked the CCRHB for the opportunity to talk about the TBHD team and its efforts.

Discussion

Dr. Coots was intrigued by Dr. Lee's work on virtual reality. He suggested collaborating with a U.S. Department of Veterans Affairs (VA) roundtable because of crossovers in terms of VR research interests. Dr. Wallen said that the NIH team is working closely with a research group at Walter Reed National Military Medicine Center on cognitive behavioral therapy for improving sleep. Dr. Coots offered to make connections for potential synergy between NIH and the VA.

Mr. Baum asked whether Dr. Wallen has looked at virtual and augmented reality in the context of Parkinson's disease. Dr. Wallen volunteered to look into this possibility, because the group is interested in identifying other patient populations to include in research. Several organizations

have come in and talked to TBHD scientists. So far, the scientists are focusing on high-risk caregiver groups, such as women over 65 who are taking care of a family member who is not their spouse, such as a parent. Testing VR interventions in different populations would be interesting. Mr. Baum pointed out that there is a large population of caregivers for people who have Parkinson's disease.

Ms. Royster asked about the cost of portable EEG devices. Dr. Wallen said that the device is new and has 64 leads. TBHD scientists are going to test its accuracy in a pilot. Other studies have shown that mobile devices can capture a great deal of data, but some patients within the community have said they do not want to end up with a lot of glue in their hair.

Clinical Center Leadership Development

Charlotte Pak, M.A., Chief, Office of Workforce Management and Development (OWMD)

During the last CCRHB meeting, Dr. Cunningham had raised an important question that was the impetus behind this presentation. Dr. Cunningham was interested in learning about existing CC programs that aim to develop internal candidates for leadership roles. Ms. Pak's presentation focused on leadership development in the CC and at NIH.

Ms. Pak said that the CC is committed to offering opportunities for leadership development to all current employees through a number of internal and external programs. Interest and participation in these programs have grown significantly over last few years, partly because of increased communication regarding opportunities and support from senior leadership. In addition, Ms. Pak said that leadership development is a key component of the CC's strategic plan.

Ms. Pak reviewed some internal and external leadership development programs and the CC's culture of investment in its staff.

CC Leadership Development Programs

The CC environment is very complex, involving both research and clinical care in a federal environment. The CC has offered leadership training since about 2005, and the Fundamentals of Supervision (FOS) program was established in 2011. So far, 242 supervisors have gone through the FOS program. FOS focuses on the technical and management skills needed to excel in a federal workplace. The leadership development program started as a full-year program but has been streamlined since then; it is currently a 5-month program delivered in nine sessions. To facilitate integration, the cohort size is limited to 20 to 25 participants. The course is tweaked annually based on current guidance. The sessions are geared to help participants build competencies in performance management, administrative management, and building teams and coalitions.

Ms. Pak said that the Fundamentals in Leadership (FIL) program was established in 2019. It consists of six sessions in a 3-month period. Each cohort includes about 20 formal or informal leaders who learn about collaboration, self-awareness, and leadership. Each session entails spending an entire day out of the office, with reading and activities between sessions. Participants do not have to be official supervisors to participate in FIL; some may be leading initiatives within their organization even though they are not supervisors. Some FIL participants have also become supervisors after participating in the program.

Ms. Pak said that the first two FIL sessions focus on self-awareness ("Leading Self"), the next two cover "Leading Others," the fifth is dedicated to "Leading for Results," and the sixth is on "Building Coalitions." After taking part in FIL, alumni may participate in ongoing learning and development opportunities, including the award-winning CC Leadership Lunch and Learn series.

In addition to FOS and FIL, the CC offers ad hoc opportunities to all staff to help them develop leadership skills. Ms. Pak listed several examples, including conflict resolution, DEIA workshops, and project management. The new monthly Supervisors' Administrative Forum is available for about 250 supervisors to learn administrative best practices and ask experts questions related to policies, procedures, and guidance.

NIH Leadership Programs

In addition to CC leadership development opportunities, NIH offers programs for midlevel, senior, and executive leaders. These courses cost between $5,000 and $17,000. Waitlisted people usually get to participate the following year. In some cases, funding or partial funding is available for graduate or postgraduate degrees, as well as for professional society memberships or fellowships.

Ms. Pak said that the Deputy Director for Management Seminar Series is free and open to all staff. The NIH Management Seminar Series consists of seven monthly seminars for high-performing General Schedule (GS) 7–12 and nonsupervisory GS-13 employees. A variety of NIH Training Center leadership development courses are offered to NIH staff at varying costs. External programs may include graduate and postgraduate degrees, university executive leadership programs, and educational programs and fellowships offered through professional societies.

NIH leaders may avail themselves of executive and leadership coaching. An internal OWMD consultant serves as an organization development consultant and strength coach. NIH leaders often request consultations and coaching.

Individual Development Plans (IDPs)

Ms. Pak reported that IDPs were launched in accordance with the 2019 CC strategic plan for all CC federal employees. An IDP is a tool to help support, plan, and track professional development and learning opportunities, and—most important—foster conversations between supervisors and employees around goals and growth opportunities. To emphasize growth, not performance, the IDP process and discussion do not occur in the context of performance management.

Conclusion

Ms. Pak said that the CC is committed to a culture of learning and investment in people through support for professional and leadership development at all levels of the organization.

Discussion

Dr. Chin said that negotiation skills are very important for clinical staff/leaders, yet little relevant training is provided in medical school. He suggested that the CC could expand education and training opportunities to include negotiation skills. Ms. Pak agreed that this is a good idea and

said it might be possible to enhance that aspect of program offerings. OWMD is working on redesign and lessons learned through the pandemic and on enhancing focus on DEIA.

Dr. Freischlag asked about continuing the cohorts for mutual support in the future. Ms. Pak said that OWMD recommends that cohorts stay in contact and also runs activities for alumni. Mr. Baum suggested setting up online forums to encourage continuing interaction within the cohorts. Pak's group is hiring some new staff, which should make it possible to expand opportunities for continuing the cohorts' activities.

Mr. Baum asked about leadership development for fellows. Ms. Pak responded that the NIH Office of Intramural Training and Education offers training for fellows.

Mr. Baum inquired about opportunities for CC volunteers. Ms. Pak said that there is no specific program for volunteers. Mr. Baum suggested offering volunteers greater access to training and development, perhaps through the Office of Hospitality and Volunteer Services. Ms. Pak thought that online trainings for volunteers might be easier to set up than in-person events. Many more people could take part in online trainings. Mr. Baum mentioned management and technical training that he has participated in.

ARPA-H: The Mission

Jennifer Roberts, Ph.D., Director, Resilient Systems Office, ARPA-H

Dr. Roberts, who was previously with the White House Office of Science and Technology Policy, introduced ARPA-H and spoke about how the CC could support the work of this new agency.

Overview of ARPA-H

Dr. Roberts explained how ARPA-H fulfills President Biden's vision of identifying areas where technical breakthroughs in the commercial world can accelerate better health outcomes for everyone by closing gaps and moving developments from the laboratory to the real world. ARPA-H staff care deeply about access and affordability and want ensure that interventions benefit populations who need them the most.

Dr. Roberts explained where ARPA-H fits within HHS and how its programs have highly specific aims and tend to be supported through contracts rather than awards. ARPA-H is disease-agnostic and does not have any internal laboratories. The ARPA-H director reports directly to the HHS Secretary.

ARPA-H is a problem-focused organization with unique structures and legal authorities that allow ARPA-H to function like a business—quickly, nimbly, and decisively. The agency can pull in experts who have revolutionary ideas. Legal authorities allow rapid funding of ideas. Flexibility in hiring allows ARPA-H to compensate top performers at levels competitive with industry. Decision making is from the bottom up. Project managers have autonomy to make decisions quickly.

Attributes of ARPA-H

Dr. Roberts highlighted unique organizational characteristics of ARPA-H:

- Project managers are the nucleus of the organization. Leaders "work for" the project managers to facilitate success. Project managers are responsible for the full program life cycle, from proposal to transition—usually about 2 to 4 years per project.
- "Radical change" is ARPA-H's watchword. Evolutionary proposers need not apply. ARPA-H investments seek to address seemingly impossible barriers in demonstrating proof of concept for solutions to major challenges—not incremental advances.
- Autonomy is key. Workshops and consultations are encouraged, but there are no advisory committees. Project managers practice "full-contact" management with metrics and milestones for programs and are empowered to stop underperforming projects.
- Term limits are a very unique aspect of ARPA-H, which is a "projects" agency, not a career. Program managers tend to start two or three programs and pull in experts as needed. Terms for project managers, directors, and deputy directors are limited to 3 years and may be renewed once, for a total of 6 years. Term limits facilitate the flow of new ideas and create a sense of urgency.

Project managers are uncommon people with common traits, including recognized expertise, insatiable curiosity, interdisciplinary track records, decisiveness, serious drive, no fear of failure, technical honesty, and a customer-centric attitude. They can take different approaches and may be at different career stages.

Program Development and Mission

To shape the portfolio, ARPA-H wants a principled way to ensure that it is investing strategically to solve well-defined problems. The Heilmeier questions are adapted from the Defense Advanced Research Projects Agency (DARPA) and being applied to health.

Program formation is led by the program manager, who identifies a difficult health-related challenge that is ripe for a solution. The challenge should not be easily solvable through traditional activities. A program manager seeks and oversees several groups of parallel performers, all aiming to solve the same problem in unique ways.

Throughout program formation, metrics and evaluations are developed for evaluating the solutions to learn which ones work in the real world. The Project Accelerator Transition Innovation Office (PATIO) seeks transition paths to increase the probability at each step that the solutions go to companies or government organizations to ensure that the solution is used in the real world.

Dr. Roberts outlined the agency's initial mission focus areas:

- ***Health science futures.*** Accelerate advances and remove limitations that stymie progress toward solutions. These tools and platforms would apply to a broad range of diseases.
- ***Scalable solutions.*** Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.
- ***Proactive health.*** Create new prevention capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats—viral, bacterial, chemical, physical, or psychological—to Americans' health.

- **Resilient health.** Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.

Dr. Roberts said that the top priority is to hire program managers who will bring well-defined problems to ARPA-H and build the teams to solve them. The agency is required by statute to have three different locations: one in the Washington, D.C., area and two others to reach patients and clinicians using a hub-and-spoke network system, including hospitals and community health centers and a network of investor-catalysts to bring technologies into use.

Dr. Roberts announced that the first program to be launched is on tissue regeneration in osteoarthritis, with the goal of reducing the need for surgery. Technology focus areas include needle-based and/or noninvasive bone and cartilage regeneration and replacement joints built from human cells. A hybrid Proposers' Day for interested research teams was held on June 15, 2023. The program's Broad Agency Announcement will close on July 28, 2023.

Discussion

Mr. Baum said that ARPA-H sounds like a cross between a venture capital (VC) organization and an agile business approach. Dr. Roberts said that she agreed to a certain extent, but she noted a key difference: ARPA-H might have a VC approach eventually, but VC organizations focus on making money. Generating money is not an aim of ARPA-H, although some projects might lead to de-risking of technologies. Mr. Baum clarified that the VC comparison mostly applies for the exit strategy approach.

Dr. Samitt supported ARPA-H's concept of telling evolutionary proposers that they need not apply. He also asked how ARPA-H will decide which problems to take on, since there is a large universe of ideas. Are there evaluation criteria or an assessment process? Dr. Roberts explained that project managers need to be able to articulate the current state and identify why the problem has not been solved yet. At this early stage, there is a great deal of potential to pull in programs, but it is also necessary to balance risk over time across disease and technology areas.

Dr. Samitt asked whether there be many projects ongoing at a given time. Dr. Roberts said that the agency works with candidates one on one to refine their ideas before the in-person interview. By the interview stage, staff have a good idea of whether there might be a program that will work. ARPA-H has the capacity to deal with 50 projects at a time.

Dr. Cunningham asked about the selection of ARPA-H sites. Dr. Roberts said that the agency is looking for geographic distribution in order to meet patients where they are and to bring in relevant demographics. Consortium management firms are in discussion, but all sorts of organizations are welcome to be considered.

Ms. Reel thanked Dr. Roberts for a great presentation that answered many questions.

Dr. Devaskar spoke of the potential for ARPA-H to seek health solutions for common and rare disorders. In some areas— especially the pediatric population—could ARPA-H have a significant impact? Dr. Roberts said that the agency is actively hiring in the area of pediatrics, which is very interesting. Progress has been impeded by issues related to incentives as well as

technology development in the pediatric space. There is a great need for solutions to improve the ability to move interventions into pediatric populations.

Dr. Gilman said he appreciated Dr. Roberts's willingness to present to the CCRHB on ARPA-H. Dr. Coots posed a question about how ARPA-H will interact with the CC, and that led to the invitation to Dr. Roberts to attend the meeting. Dr. Gilman said that each IC has established a point of contact to serve as a go-between for ARPA-H. Dr. Gilman fills that role for the CC.

Dr. Gilman recalled that ARPA-H staff reached out to identify CC staff who may be relevant experts for ideas. The CC will give ARPA-H information and authorize access to subject matter expertise. ARPA-H might not know some things about the CC, for example, and that expertise in bone and cartilage science can be found not only in the National Institute of Arthritis and Musculoskeletal and Skin Diseases but also in NIDCR. Dr. Gilman gave ARPA-H access to CC expertise and suggested other places where they might want to look for experts. That is the only interaction between the CC and ARPA-H to date, but Dr. Gilman anticipates more over time. Dr. Roberts said that the points of contact provided by Dr. Gilman have been very helpful already.

Dr. Coots thanked Dr. Roberts for the fascinating presentation. He asked ARPA-H staff to provide periodic updates to the CCRHB, especially as the agency begins work with ICs and the CC.

Closing Remarks

Dr. Coots thanked everyone for an excellent meeting. He said the final meeting this year would be on October 20. The 2024 schedule is forthcoming.

Adjournment

Dr. Coots adjourned the meeting at 12:37 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, CCRHB

Acting Principal Deputy Director, NIH

Abbreviations and Acronyms

ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ARPA-H	Advanced Research Projects Agency for Health
BRAIN	*Brain Research Through Advancing Innovative Neurotechnologies®*
CC	Clinical Center
CCND	Clinical Center Nursing Department
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CNO	chief nurse officer
COVID-19	coronavirus disease 2019
CWG	Children's Working Group
DARPA	Defense Advanced Research Projects Agency
DEIA	diversity, equity, inclusion, and accessibility
EEG	electroencephalogram
FIL	Fundamentals in Leadership
FOS	Fundamentals of Supervision
FRA	Fiscal Responsibility Act of 2023
FY	fiscal year
GS	General Schedule
HHS	U.S. Department of Health and Human Services

NCI	National Cancer Institute
NIDCR	National Institute of Dental and Craniofacial Research
NIH	National Institutes of Health
OAR	Office of AIDS Research
OWMD	Office of Workforce Management and Development
PAG	Patient Advisory Group
PATIO	Project Accelerator Transition Innovation Office
PDS	Pharmaceutical Development Service
PPG	Pediatric Planning Group
REEP	racial and ethnic equity plan
SRLM	Surgery, Radiology, and Laboratory Medicine (wing)
TBHD	Translational Biobehavioral and Health Disparities Branch
UCLA	University of California, Los Angeles
VA	U.S. Department of Veterans Affairs
VC	venture capital
VR	virtual reality