

U.S. Department of Health and Human Services  
National Institutes of Health

# Thirteenth Meeting of the Clinical Center Research Hospital Board

July 19, 2019

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## **Clinical Center Research Hospital Board**

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital; and Chair, National Institutes of Health (NIH) Clinical Center Research Hospital Board (CCRHB)

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; and Executive Director, CCRHB

Francis S. Collins, M.D., Ph.D., Director, NIH; and *Ex Officio* Member, CCRHB

Ellen Berty, Special Education Teacher, Book Author, and Former NIH Research Participant

Beatrice Bowie, Facilitator, Sickle Cell Support Group, Adventist HealthCare Shady Grove Medical Center; and Board Member, NIH Patient Advisory Group

\*Ruth Brinkley, M.S.N./Adm., KentuckyOne Health

\*Brig Gen James Burks, M.B.A., M.M.A.O.S., Director, Manpower, Personnel, and Resources, and Chief, Medical Service Corps, U.S. Air Force

Jeanette Erickson, D.N.P., RN, FAAN, Senior Vice President for Patient Care Services and Chief Nurse, Massachusetts General Hospital (by telephone)

Stephanie Reel, M.B.A., Chief Information Officer, Johns Hopkins University and Health System

Richard Shannon, M.D., Executive Vice President, Health Affairs, and Professor of Medicine, University of Virginia Health System

\*Reed Tuckson, M.D., Managing Partner, Tuckson Health Connections

\*Absent

## **Executive Summary**

The 13th meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on July 19, 2019, on the main campus of NIH. The meeting was open to the public and webcast live.

Before the opening of the meeting, the CCRHB members toured the Clinical Center.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer of NewYork-Presbyterian Hospital and Chair of CCRHB, called the meeting to order at 10:00 a.m. ET and welcomed everyone in attendance.

Francis Collins, M.D., Ph.D., Director of NIH, mentioned several groups of high-profile visitors who have recently toured the Clinical Center. He also announced that the staff of the new Clinical Center hospice received an NIH Director's Award for their contributions in helping patients and their families. Dr. Collins presented some initial findings from the NIH Workplace Climate and Harassment Survey of the intramural workforce and underscored the importance of ensuring that NIH provides a safe and supportive work environment, free of harassment, for all employees, but especially women.

Clinical Center facilities was the topic of a presentation by Dan Wheeland, Director of the NIH Office of Research Facilities. He showcased many construction and renovation projects within and outside the Clinical Center, all of which are designed to improve patient safety, support cutting-edge research, and enhance patient care.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, updated the Board on accomplishments since the Red Team's report and areas that are in need of improvement. He provided data on the hospital's average daily census, noting that the year's high (159 patients) had been reached this week. He also presented the Clinical Center's new strategic plan, the culmination of 2 years' work by many stakeholders.

Jonathan M. Green, M.D., M.B.A., spoke about progress with the restructuring and centralization of the intramural institutional review board (IRB) system. The 12 original IRBs are being replaced by a single IRB with flexible committee membership and dynamic scheduling. The results should be increased efficiency and better-quality reviews.

The meeting concluded with a presentation by Laura Lee, RN, Chief of the Office of Patient Safety and Clinical Quality, who briefed the CCRHB on a recent unannounced Joint Commission survey and presented benchmarked data on safety and quality metrics.

Dr. Forese thanked the Board members for attending and sharing their insights. She adjourned the meeting at 1:47 p.m.

The next face-to-face CCRHB meeting is scheduled for October 18, 2019.

# Meeting Summary

## Friday, July 19, 2019

### **Welcome and Board Chair's Overview**

*Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital; and Chair, Clinical Center Research Hospital Board (CCRHB)*

The 13th meeting of the CCRHB took place on July 19, 2019, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and webcast live.

Before the meeting, the CCRHB toured several areas of the Clinical Center, including the new hospice unit, a clean room in the pharmacy, and renovated patient rooms.

Dr. Forese called the meeting to order at 10:12 a.m. ET and welcomed all present. She announced that Richard Shannon, M.D., was participating via teleconference.

Dr. Forese thanked Douglas Lowy, M.D., Acting Director of the National Cancer Institute (NCI) and Chair of the Clinical Center Governing Board (CCGB), for attending the meeting.

### **NIH Director's Remarks**

*Francis Collins, M.D., Ph.D., Director, NIH*

Dr. Collins reported that he and Dr. Forese have discussed bringing on new members to serve on the CCRHB. He spoke of the importance of balancing expertise, geography, and diversity among the members.

### ***Clinical Center Visitors***

Dr. Collins said that many people have been visiting NIH and touring the Clinical Center. Members of two congressional delegations—the Congressional Cancer Survivors Caucus and the New Democrat Coalition—had visited earlier this week. He also attended a recent New Democrat Coalition luncheon, which was attended by 61 members of Congress who were interested in learning more about NIH. Dr. Collins also announced that two high-ranking officials within the U.S. Department of Health and Human Services (HHS) would be touring the Clinical Center later in the day.

### ***NIH Recognitions***

NIH Director's Awards are given to people who work at NIH in recognition of their excellence and exemplary contributions. During the ceremony earlier this week, an award was given to staff who designed and implemented the Clinical Center's hospice unit, which has been a great contribution to patient care.

### ***New Opportunities for Cell-Based Therapies***

Much excitement centers on recent advances in cancer immunotherapy and gene therapy, according to Dr. Collins. The *60 Minutes* segment on gene therapy for treating sickle cell disease has led to many people wanting to come the Clinical Center for interventions. The program showcased the gene therapy approach for curing sickle cell disease developed by John Tisdale, M.D., of the National Heart, Lung, and Blood Institute (NHLBI). Dr. Collins recalled that the

very first gene therapy was given at the Clinical Center nearly 30 years ago; its potential has blossomed in recent years.

Clinical Center leaders need to start planning now to leverage opportunities to develop cell-based therapies for treating cancer and other diseases. Dr. Collins mentioned the need for facilities to support current good manufacturing practice (CGMP) production of vectors to ensure they are available for intramural researchers for *ex vivo* and *in vivo* gene therapies, such as the recently approved treatment for spinal muscular atrophy that corrects the genetic defect at the most fundamental level: the DNA itself.

### ***Ensuring a Safe and Supportive Work Environment***

Dr. Collins underscored the essential nature of the Clinical Center workforce and the importance of ensuring a safe and supportive working environment, free of harassment for all employees, but especially women, as they are important contributors to science. A [2018 report from the National Academies of Sciences, Engineering, and Medicine](#) (the National Academies) shone a light on the pervasive and continuing problem and consequences of gender harassment in the academic sciences, engineering, and medicine. Dr. Collins announced that Lawrence A. Tabak, D.D.S., Ph.D., has assumed a leadership role in NIH's efforts to address gender discrimination.

NIH conducted the rigorous NIH Workplace Climate and Harassment Survey of the intramural workforce to learn about employees' experience with gender harassment. The response rate was close to 60%, but the [interim results](#) were sobering. More than 20% of respondents said they had experienced harassment in the prior year. The harassment often came in the form of subtle put-downs or not being treated as equals. Women most often reported being subjected to harassment. Although the survey was completely anonymized, some correlations indicated where problems were more prevalent.

Dr. Collins pointed out that women need more opportunities to serve in leadership roles at NIH. Many branch and laboratory chiefs are men who, in some cases, have held those positions for many years. Discussions are centering on the idea of putting time limits on these positions to open up more opportunities. There has been some pushback from individuals who have served in leadership roles and have done a good job, but this change would make the whole NIH enterprise more welcoming, vibrant, and successful.

Dr. Collins thanked the CCRHB for its continuing help with managing the Clinical Center, and he introduced the agenda for the day's meeting.

### ***Discussion***

Dr. Forese thanked Dr. Collins and other intramural leaders for taking the issues of harassment and gender discrimination seriously. In response to a question from Dr. Forese, Dr. Collins said that of NIH's 27 Institutes and Centers (ICs), 10 have Directors who are women—the most ever in the history of NIH. He mentioned that Patricia Flatley Brennan, R.N., Ph.D., Director of the National Library of Medicine, recently conducted brief interviews with the female IC Directors.

## Clinical Center Facilities Update

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

Mr. Wheeland highlighted important developments in the NIH facilities program that have commenced or been completed since he presented to the CCRHB in April 2019. He noted that the budget for fiscal year (FY) 2019 represented an increase from \$128.6 million to \$200 million. Also received was \$100 million in Nonrecurring Expenses Fund (NEF) resources. Another important development since his last presentation to the CCRHB was a contract between NIH and the National Academies to convene an *ad hoc* committee and prepare a report [assessing the capital needs of NIH's main campus](#). The draft report is due in July 2019. NIH leaders and staff hope that the report will enhance the odds of additional facilities funding.

### ***Projects Outside of the Clinical Center***

Mr. Wheeland described several critical infrastructure projects outside of the Clinical Center complex. The projects would enhance patient safety in the event of disruptions of local water supplies or electrical service:

- **Industrial water storage:** The water stored in the tank could supply 5 million gallons of make-up water (a full day's supply under extreme conditions) for generating steam or chilled water until the municipal supply is restored. This project is completed and operational.
- **Thermal energy storage system:** In the event of electrical power loss, this 7.5 million-gallon "shock absorber" could provide 1 day's worth of chilled water to maintain proper temperatures and humidity levels to avoid affecting patient safety or animal research. This project is completed and operational.
- **Black start generators:** Local power outages could disrupt steam generation on campus. Black start generators would permit the operation of NIH's 23-MW cogeneration plant, which would enable NIH to continue to generate steam and chilled water to critical patient care areas in the Clinical Center should a power outage occur. This capability would go above and beyond Joint Commission requirements and give NIH a more resilient posture for handling power disruptions. The cogeneration plant consumes natural gas to generate steam and electricity. This project has been funded and is now being designed.
- **Utility vault and patient parking garage:** The Clinical Center currently has outdated electrical infrastructure housed in relatively vulnerable structures. Furthermore, having patient parking under the hospital complex is a security risk. The utility vault portion of this project will provide the safe structure in which to house the electrical infrastructure described in the next project. This project has been funded. Proposals for a design-build contract are being solicited. The project is scheduled to be awarded in September 2019 and completed by September 2021.
- **Electrical power supply replacement and upgrade:** The hospital complex's emergency generator and switchgear equipment are outdated, being more than 20 years old. New equipment will make the facility more reliable. The plan is to request Non-Expiring

Expenses Funds (NEF) resources to support this project. Bridging documents are being prepared for the project, which should get under way during FY 2021.

### ***Projects Within the Clinical Center***

- **Replacement of heating pipes:** Mr. Wheeland described the pipe failure on the 14th floor, which caused leaks and disruption to operations in the outpatient clinics on the floors below. All the piping and couplings were replaced, reducing the likelihood of future flood events.
- **Replacement of chilled water pipes:** In a similar project, the chilled water pipes were also replaced on the 14th floor.
- **Building 10 fire alarm control upgrade:** This phased project is transforming the legacy XLS fire alarm control system to a new MXL system. The project has been funded and is underway.
- **Chemical-based effluent decontamination system (EDS) for the Special Clinical Studies Unit (SCSU):** A patient with a highly pathogenic contagious illness, such as Ebola virus disease, may generate up to 9 L per day of infectious liquid waste. The EDS will improve safety by disinfecting wastewater prior to discharge to sanitary sewer lines. This project has been funded and should be completed by December 2019.
- **Renovation of the E-Wing:** The renovated and modernized facilities, including cell-processing laboratories, will support cutting-edge research when completed in early 2022.
- **Division of Transfusion Medicine's cell-processing modular facility:** Additional CGMP space will support expanded aseptic cell processing and engineering functions. However, Mr. Wheeland explained that the June 2020 target completion date is in jeopardy because of a 7-month delay in manufacturing the modular units.
- **NCI tumor-infiltrating lymphocyte (TIL) facility:** This new facility is being manufactured by the same entity that is setting up the cell-processing modular facility, so Mr. Wheeland anticipated that the TIL facility might also be subject to delay.
- **The NCI viral vector and CGMP modular trailers:** Mr. Wheeland reported that these facilities have experienced delays due to electrical/mechanical logic problems with validation procedures. In order to avoid future delays, we have entered into a contract with a firm out of Frederick, MD, to conduct independent testing of the control logic.
- **Department of Laboratory Medicine's (DLM's) Sterility Laboratory:** This project has been funded, and the project should be completed during the summer of 2020.
- **Expansion of the Interim Intravenous Admixture Unit (E-IVAU):** This project will provide a temporary increase in IVAU capability until the permanent IVAU is completed. Construction is scheduled to be completed in April 2020, with commissioning and qualification or validation scheduled for June 2020. Mr. Wheeland explained that the Food and Drug Administration (FDA) made suggestions regarding the design, and those suggestions are being adopted. He did not anticipate any delays with this project.

- **Building 10 Electrical Vault 10 upgrade:** This project, supported with NEF resources, is intended to improve electrical system safety and reliability for the Clinical Center and research laboratories.
- **Pharmacy and Permanent IVAU renovation:** This \$50 million project entails a complete gutting of the pharmacy space and construction of a new penthouse with a dedicated air handling system. All pharmacy operations will be moved to another space during the renovation, which will improve patient safety and regulatory compliance. The project has been funded, and the contract will be awarded at the end of FY 2019. We estimate completion May 2021.
- **Upgrade of the building automation system (BAS) in the Clinical Research Center (CRC):** The BAS is outdated and no longer supported by the manufacturer. This project will reduce the risk of cyber intrusion and improve temperature and humidity control in the CRC. The project requires careful coordination while transitioning from a legacy system to a new, automated system.
- **Radiopharmacy and Biologics Radiolabeling Project:** The existing facility is inadequate to meet FDA and USP requirements for combined sterile compounding and radiolabeling work. This project has been submitted for FY 2020 funding. A recent briefing of FDA went well, although FDA recommended having a separate exit in one space to avoid cross-contamination. This might not be feasible, however, because of space limitations.
- **Surgery, Radiology, and Laboratory Medicine (SRLM) building:** SRLM services are currently located in obsolete facilities built during the 1980s. Mechanical, environmental, and plumbing infrastructure can no longer be upgraded economically. This project will provide modern space for the Department of Laboratory Medicine, the Department of Perioperative Medicine, the Department of Radiology and Imaging Sciences, a cardiac catheterization laboratory, and interventional radiology. The facility will be state of the art, highly functional, and in harmony with the design of other buildings on the NIH campus. Mr. Wheeland said that the Program of Requirements has been validated already; design will take about 18 months. FY 2020 NEF resources have been requested. Once the funds are in hand, the project probably will be completed within approximately 5 years, providing safe, compliant, maintainable, and flexible facilities to support cutting-edge science and optimal patient care. Including the cost of medical equipment, the cost is likely to be approximately \$575 million.

Mr. Wheeland concluded by saying that the renovation and construction projects will improve patient safety, the environment of care, and life safety. Furthermore, he hopes that the National Academies' report will validate the need for new NIH facilities to support safe, reproducible biomedical research.

### ***Discussion***

- Regarding the cost drivers for the SRLM building, Mr. Wheeland explained that new federal buildings are required to have an architectural design such that, in the event of

terrorism or natural disasters, the entire building will not collapse. He also explained that design and construction costs do not include the costs of medical equipment, validation, activation, and move-in. Dr. Forese thought that the projected costs seemed reasonable.

- Dr. Forese asked about the reliability and responsiveness of the local electrical power company. Mr. Wheeland recalled that some major problems occurred about 10 years ago, but conditions have dramatically improved. He said that, sometime around 2008, he had to remind the utility officials that NIH is operating a major hospital here.
- Dr. Forese asked whether the SCSU is in readiness all the time. Dr. Gilman explained that it is always ready and that, in fact, some research programs (influenza research) rely on it (e.g., the influenza program uses it). If a patient or health care provider was admitted for exposure to or infection with a viral hemorrhagic fever, for example, other research activities would be displaced. John Gallin, M.D., added that the SCSU also is useful for staff training.
- Stephanie Reel, M.B.A., asked about funding of operating expenses associated with bringing new buildings online. Mr. Wheeland spoke of significant support from the Facilities Working Group, as well as the Management and Budget Working Group. In general, budget increases have been granted to meet documented needs. Because of the number of aseptic CGMP facilities coming online, a budget increase of \$3.4 million was sought to ensure proper calibration, maintenance, work plan development, and so forth for these high-reliability facilities. The Facilities Working Group, of which Dr. Gilman is a member, has endorsed that request. In Mr. Wheeland's experience, operating funds have not been a rate limiter when it comes to construction and renovation projects. Rather, capital funds, which are overseen by Congress, HHS, and the U.S. Office of Management and Budget, have been the rate limiter. Mr. Wheeland said that, thanks to the help of many individuals and groups, the situation has improved. Dr. Gallin clarified that the activation of new buildings is not covered in capital budgets for construction. Such expenses should be planned for and submitted in advance.
- Ms. Reel asked about the potential challenge of recruiting project managers when so many projects are ongoing. Mr. Wheeland said that after project managers successfully oversee projects such as these, they become highly marketable. Other agencies sometimes have recruited NIH's top project managers, but NIH has a very special mission and is a unique place to work, which helps with retention and also recruitment of managers from elsewhere. On the maintenance front, these buildings are very complex and highly automated. This means that workers need to be well trained and sophisticated in their knowledge of building systems and controls. Mr. Wheeland said that an apprenticeship program is being developed to invest in tradespeople, who are essential for running buildings like the Clinical Center.
- Dr. Forese asked about whether *Legionella* contamination has been identified in the Clinical Center's water supply. Mr. Wheeland said that this organism can be a problem in utility plants and that the treatment of water is a science unto itself. He explained that, at the Clinical Center, real-time microbiology analysis is used to calculate the need for

chemical treatment to ensure safe water supplies. With real-time analysis, adjustments can be made almost instantaneously instead of having to wait days or even weeks to get test results back. Dr. Gilman also credited the excellent hospital epidemiologists and superb microbiologists with keeping ahead of potential environmental issues. In fact, NIH has published about some challenges with water quality in Building 10, although *Legionella* has not been a problem.

- Dr. Shannon thanked Mr. Wheeland for his comprehensive review of construction and renovation projects in the Clinical Center. He appreciated the careful project planning and asked that Mr. Wheeland keep the CCRHB updated on progress with funding and construction.

## **NIH Clinical Center Chief Executive Officer (CEO): Update**

*James Gilman, M.D., CEO, Clinical Center*

Dr. Gilman greeted the CCRHB members and updated them on various developments in the Clinical Center.

Dr. Gilman reported that he was the first IC Director (or equivalent) to be appointed since the passage of the 21st Century Cures Act, which included a change from indefinite appointments for IC Directors to 5-year renewable term appointments. This means that Dr. Gilman, who was appointed in January of 2017, is now at the midway point of his appointment as CEO of the Clinical Center.

### ***Taking Stock***

Dr. Gilman spoke of the Red Team’s findings and the responsive actions taken by NIH leadership. He highlighted some indicators of improvement in the Clinical Center since the Red Team’s report was issued:

- **Excellent 24-7 work by Clinical Center Nursing Department administrative coordinators:** The hospital census fluctuates weekly. The Clinical Center is very busy Tuesday–Thursday, but some patients are very ill and require care throughout the week. During evenings and weekends, senior nursing leaders visit other clinical services to assess status and offer support as needed. They can elevate issues to other staff members who are in positions to take action.
- **Significantly less use of the term “ancillary” to refer to staff members or groups:** In the Clinical Center, everyone is considered an important part of the team; no service is tangential. This change in terminology represents a change in culture.
- **Elevated importance of staff clinicians, midlevel providers, and nurses:** At the time of the Red Team report, these groups of employees expressed feeling unhappy and unappreciated. Staff clinicians now have tiers for advancement and promotion in their careers along with guaranteed travel funds for conferences and new award opportunities. Dr. Gilman also gave credit for sustained gains in patient safety to Gwentyth R. Wallen, Ph.D., RN, Chief Nurse Officer in the Clinical Center, and the nursing staff. NIH leaders empowered CC nurses and sought (and continue to seek) their advice and help with improving patient safety.

- **Multi-institute hematopoietic stem cell transplant (HSCT) service:** Largely driven by NCI; NIAID, NHLBI, and NHGRI, a HSCT service is being established to increase efficiencies and improve patient safety in this patient population.
- **Failure modes and effects analysis (FMEA):** NIH staff are becoming adept with FMEAs as an important way to predict and prepare for challenges—key steps in maximizing the safety of the Clinical Center’s first-in-human (FIH) studies.
- **Risk-based decision making:** Some research activities proposed for the Clinical Center have been turned down. These difficult decisions have been supported by leadership.
- **Facing challenges:** Dr. Gilman said that the Clinical Center staff takes on hard problems, (e.g., urgent patient transfer procedures and fertility preservation for young women undergoing HSCT). Dealing with infection control issues that are difficult remains a high priority.
- **Budget enhancements:** The Clinical Center’s budget for equipment and facility modifications are much improved.

Dr. Gilman acknowledged room for improvement in several areas:

- **Continuity of patient care after research:** Although rarer now, in some cases, researchers’ interest wanes after the interests of science have been satisfied. These nuanced and complicated situations influenced changes recommended in the Red Team report. Dr. Gilman said that at times, the best solution might involve transferring a CC patient to tertiary care centers once the care provided within the clinical research study is completed.
- **Professionalism and civility in communications:** Both staff and patients should be able to raise concerns without feeling intimidated or guilty. Dr. Gilman reported that Jo Shapiro, M.D., Director of the Center for Professionalism and Peer Support at Brigham and Women’s Hospital, will be speaking to the Medical Executive Committee (MEC) and during medicine grand rounds.
- **Intersection of CGMP and patient care:** CGMP regulations assure quality drug products, including drug manufacturing. This standard presents special challenges when products are needed for seriously ill patients with few treatment options.

### ***Clinical Center Census***

Dr. Gilman presented average daily census (ADC) data for the hospital. While the first week of July experienced a low ADC (100 patients per day), patient activity substantially increased after the holiday, with a recent peak day of 159. It was on the low side during the first quarter this year, but admissions ramped up in the second quarter, and the third quarter has been very busy. The 3-year ADC for 2015–2017 was 127; at the end of FY 2018, the ADC was 113. So far in 2019, the average has been 113.

### ***Recent Staff Changes***

Dr. Gilman announced that after 40 years at the Clinical Center, David Henderson, M.D., is stepping down from his positions as the Deputy Director for Clinical Care and the Associate Director for Hospital Epidemiology and Quality Improvement. Dr. Henderson was the first

hospital epidemiologist at the Clinical Center. He has served for 25 years as the Deputy Director for Clinical Care.

Dr. Gilman will launch the search for Dr. Henderson's replacement about 6 months before Dr. Henderson will depart at the end of the year. The job title is being changed to Chief Medical Officer. The search committee has already been selected.

### ***Strategic Plan***

The Clinical Center's strategic plan is entitled *People Places Capabilities: The NIH Clinical Center at 65*. Copies of the document were provided to CCRHB members in advance of this meeting. The strategic plan will be posted on the Clinical Center's website.

Dr. Gilman presented the timeline for developing the document. The project kicked off during the summer of 2017 and the process has involved 18 months of soliciting input from key stakeholders via CCGB meetings, two IC planning cycles, dozens of IC and MEC meetings, and at least a few Capitol Hill encounters. Drafting of the plan occurred during January–March this year. Dr. Gilman emphasized that the document is a high-level strategic plan, not a detailed implementation plan. It is designed to serve both internal and external stakeholders. The implementation plan will come later. The strategic aims outlined in the report are as follows:

- **Aim 1:** Continuing to lead the world in conducting FIH clinical research while maintaining a focus on rare and refractory diseases. This aim is NIH's forte. Examples include the Center for Cellular Engineering, the new program for developing cell therapies for blood and inherited diseases, and gene therapy trials. Because of its unique fiscal situation, NIH can take on these types of research.
- **Aim 2:** Increasing the use of the Clinical Center by the NIH Intramural Research Program (IRP) while accelerating the Clinical Center's status as a national resource for the extramural community. Dr. Gilman said that some new programs will address such topics as Alzheimer's disease and related disorders, pain research, and drug abuse. Dr. Gilman also mentioned a research program of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) that proposes to recruit healthy pregnant women for metabolic studies. This population has been underserved by research and excluded from nearly all studies. In the Clinical Center, there is some space available to create new programs. Legacy U01 and bench-to-bedside programs have not increased the number of research participants coming to the Clinical Center. Dr. Gilman spoke of creating virtual programs (telehealth) to reach more diverse, rural, and international populations.
- **Aim 3:** Demonstrating profound respect for our patients, whom we recognize as our full partners in the clinical research enterprise. Dr. Gilman said that this aim was recently added. NIH's Patient Advisory Group (PAG) is being expanded, and the Clinical Center is implementing and resourcing some of the PAG's suggestions. For example, there is a plan for removing the hodgepodge of cardboard signs in the Clinical Center and replacing them with digital displays. In addition, the Chief Scientific Officer is figuring out how to incorporate more input from patients, families, and advocates into research.
- **Aim 4:** Partnering with the ICs to recruit, develop, and retain the next generation of great NIH clinical researchers and the Clinical Center staff who will support their efforts. IC

representatives are involved in every key search. Support for the Medical Research Scholars Program and for talent management is a central aspect of this aim.

### ***Discussion***

- Dr. Shannon said that measuring success is important. He suggested creating a dashboard to help the CCRHB assess progress toward the four aims every year. Dr. Gilman said that measuring success will be part of the implementation plan, but he cautioned that coming up with metrics would not be easy.
- The timeframe for this plan is 5 years, according to Dr. Gilman, although many facility projects take more than 5 years for completion. Dr. Forese suggested that periodic “snapshots” would be helpful for tracking progress toward aims and for updating the plan, which should be considered a living document.
- Dr. Reel asked about the demand for beds in the Clinical Center. Dr. Gilman said that only patients who are enrolled in a research protocol come to the Clinical Center. Right now, there are 1,600 active protocols, but they do not cover every disease. Study participants have to meet very stringent eligibility criteria. Only certain patients get to the point where they are ready for an FIH trial. The Clinical Center focuses on Phase I–II clinical trials, not large Phase III trials. Intramural investigators work hard to identify subjects to demonstrate the safety of and detect signals of efficacy for investigational products.
- Dr. Shannon supported the idea of pivoting to a virtual space as an opportunity to try to close the gap between intra- and extramural research environments. Dr. Shannon has spoken with the Director of NHGRI about establishing systems to allow NIH’s medical geneticists to provide virtual consultations. Individuals who have rare variants could be referred to the NIH Clinical Center’s natural history studies. Such systems would allow the Clinical Center to partake in the disruptive virtual care model that is emerging.
- Dr. Forese referred to a section in the strategic plan about pediatric research, which presents exciting scientific possibilities, especially with cell and gene therapies, but she underscored the importance of balancing safety with scientific opportunity. Dr. Gilman said that the Clinical Center has age and size cutoff criteria for children who participate in intramural research. Pediatricians evaluate children who meet the criteria or are on the border of eligibility to ensure that the Clinical Center is equipped to care for them. There is interest among intramural researchers in working at the margins, with children who are younger or smaller but not necessarily sicker. In gene therapy, correcting the problem early in life is very important. That is why the Clinical Center undertakes an in-depth analysis to assess the ability to care for small children who need this treatment. Dr. Gilman said that the Clinical Center has a good relationship with the Children’s National Medical Center. Clinical Center pediatric staff have identified some training that would help them care for children. He said that there are some hard limits, however. For example, the IRP is not in a position to open a pediatric intensive care unit in the near future, nor can neonates or preterm infants be treated at the CC.

- Dr. Forese thought that research involving pregnant women could be a very interesting niche for the Clinical Center. Dr. Gilman pointed out that pregnant women are in the Clinical Center all the time, as staff members, but are not supposed to deliver there. With regard to running trials that recruit and enroll pregnant women, Laura Lee, RN, is carrying out FMEA to understand potential problems, such as the possibility of pregnant women coming to the Clinical Center with pregnancy problems. Dr. Gilman emphasized that partnerships with hospitals in the area and transportation plans would have to be set up to ensure that enrollment of pregnant women in clinical studies here could be done safely for such protocols.
- Dr. Forese asked about Clinical Center's support of studies on opioid addiction, pain research, and related topics. Dr. Gilman said that some imaging studies are already being carried out in the Clinical Center, and he added that some patients can be hospitalized in the National Institute on Alcohol Abuse and Alcoholism unit. Recently, the National Institute on Drug Abuse, which has its clinical facility in Baltimore, indicated that more support might be needed from the Clinical Center. If patients will be coming to the Clinical Center in larger numbers, planning and other work will be necessary.

#### ***Follow-Up Items***

- The CCRHB asked Dr. Gilman to invite Dr. Henderson to the next CCRHB meeting.
- The CCRHB suggested conducting a gap analysis to figure out what would be needed to support more pediatric research at the Clinical Center.

### **Office of Human Subjects Research Protections (OHSRP) and NIH Intramural Institutional Review Board (IRB) Program**

*Jonathan M. Green, M.D., M.B.A., Director, OHSRP*

Dr. Green introduced himself. He had served for 22 years on the faculty at Washington University in St. Louis, where he had many different roles. He thinks of himself primarily as a physician trained in internal medicine, but he was also a basic researcher. Dr. Green became interested in bioethics while working in the intensive care unit (ICU). He joined the hospital's ethics committee and was later appointed its Chair. Dr. Green was then recruited to join the IRB and later became the Executive Chair of the IRB, overseeing one of the largest research programs in the country. He joined NIH in 2018.

Dr. Green described the plans being implemented to reorganize and rebuild the IRB system that oversees the IRP. The goal is to create an efficient, high-quality IRB to review NIH intramural human subjects research. The Human Research Protection Program (HRPP) should provide optimal participant protections with consistent and regular reviews that comply with regulations. Educational outreach is another important component of the HRPP.

Dr. Green said that the regulatory environment is becoming increasingly complex. The Common Rule was just revised. Changes in FDA and U.S. Department of Defense regulations, the Privacy Act, NIH policies, and the single IRB mandate are coming soon or being implemented now.

At the start of the reorganization effort, 27 ICs were served by 12 IRBs managed by 12 administrative offices. The IRBs had 12 different processes with oversight by IC leadership, resulting in inefficiency and inconsistency in the quality of the reviews and the extent of IC control. The reorganization effort is aiming to have one IRB, one central administrative office, and one way of doing things. The IRB will be truly independent, with appropriate separation from the research itself.

Dr. Green explained the three main steps involved in the IRB organization: revising HRPP policies, standing up the centralized administrative office, and reorganizing the IRBs.

### ***HRPP Policy Revision***

Policies are being simplified to help investigators understand them better. The focus is on policy, not operations. All policies had to be updated anyway to comply with the revised Common Rule.

### ***Centralized Administrative Office***

Dr. Green compared the prior and current organizational charts for IRB administration. OHSRP is being converted to the Office of Policy, and a new Office of IRB Operations is being set up. The Office of IRB Operations is directed by Tiffany Gommel, M.S., CIM, CIP, who was recruited from outside of NIH. Heather Bridge is managing the Office of Policy, which is responsible for continual evaluation and development of policy. Compliance is now centralized in this office. The staff triage reportable events to see whether anything needs to be done quickly to protect participants. They also manage noncompliance investigations.

The new Office of Compliance and Training is managed by Peg Sanders, M.A. The main goal of this office is to create and implement educational programs for NIH investigators.

### ***IRB Restructuring***

Dr. Green presented a diagram depicting system inefficiencies in the former IRB system. The time from submission to approval of protocols was highly variable, but it could be many months in some cases. The first and foremost problem was that the committees were getting applications that were not ready. There was a second bottleneck because agenda items had to be batched for the IRB meetings. Structural changes are being implemented to increase efficiencies.

To make sure that submissions are ready for review, professional IRB analysts who know the regulations make sure that all required documents are submitted and that they provide all the necessary information. The analysts will detect any red flags, which would tell Dr. Green or Ms. Gommel to work with the investigator to fix problems that would be impediments to approving the protocol.

To deal with the other bottleneck, the IRB meets more frequently, allowing items to get on a meeting agenda sooner. Eventually, IRB committees will meet six times per week. Because the materials have already been vetted, the panels can focus on the criteria for approval.

In the past, the IRP had 12 IRBs, all working in isolation, each with a unique culture and emphasis on different aspects of human subject's research. With the restructuring, there will be just a single, flexible IRB structure. Each committee meeting will involve nine IRB members, comprising three physician-scientists, four nonphysician scientists, and two nonscientists. The quorum for each meeting is five members, including at least one nonscientist member. The

committees are completely flexible with a dynamic makeup. A few people are designated as primary members, and the remainder are alternates. Members have a week to review the protocols.

Every committee is different, so how can appropriate expertise be ensured at each meeting? Dr. Green gave an example of a protocol on prostate cancer that has been screened by the analysts for completeness. It is then scheduled for an IRB committee review. The 160 IRB members schedule themselves for meetings online. When the study comes through, it is assigned to a committee that has an expert in prostate cancer. Dr. Green could also call an *ad hoc* expert or arrange for a written consultation. He said he could also anticipate the necessary composition of the IRB. If, for example, 25% of protocols are in the cancer field, then he would know that 25% of IRB members need to be cancer experts to ensure that necessary expertise is available.

The IRB chairs can help provide consistency. They exert leadership and keep the committees on track. They focus the panels on criteria for approval as set forth in the regulations.

### ***Research Compliance Review Committee***

A separate committee with fixed membership evaluates regulatory compliance of intramural protocols. The Research Compliance Review Committee is a duly convened IRB with the authority to approve, suspend, or terminate protocols. The committee makes determinations of serious and/or continuing noncompliance. The goal is to identify problems that need to be fixed and help support the research team so it can move forward with the study.

### ***Progress to Date***

Dr. Green said that the Office of IRB Operations has hired about 50% of the needed staff, but not all of those hired have been onboarded. The new IRB is registered with OHRP and has been reviewing all new protocols since January 21, 2019. Since then, older protocols have been transferred to the central IRB from the original intramural IRBs. The goal is to have all protocols brought into the new IRB structure by the end of 2019. Relevant policies have been revised, and the Research Compliance Review Committee has been established. Dr. Green hopes that all positions in the new structure will be filled by the end of August. Onboarding takes a great deal of time. Much work remains. Dr. Green underscored the importance of this reorganization, saying that NIH cannot fulfill its mission if it cannot do clinical research efficiently. The new IRB system will enhance the ability of NIH to accomplish its mission.

### ***Discussion***

- Dr. Forese asked about the single IRB mandate. Dr. Green explained that if a multisite study takes place, typically, each site would have its own IRB. Now, under the new regulations, any multisite study will be overseen by a single IRB. All sites sign an agreement to defer to the selected IRB. The first mandate was instituted by NIH in the spring of 2018 for all NIH-funded multisite studies. The Revised Common Rule regarding the single IRB mandate will come into effect in 2020. Each individual site is still responsible for the conduct of research at its site, but actual IRB review is done by one IRB. Under the prior system, sponsors had to negotiate with many IRBs regarding informed consent documents, so the single IRB mandate has improved efficiency of

research. However, it has been challenging to implement the mandate because of the complexity of the research enterprise.

- Jeanette Erickson, D.N.P., RN, FAAN, said that the new IRB structure is an excellent and efficient model. The scheduling piece for the IRB meetings is brilliant. Dr. Green responded that the same sort of system rolled out at Washington University in St. Louis back in 2013. The new IRB system requires a new mindset and resources.

#### ***Follow-Up Item***

- Dr. Shannon suggested that Dr. Green share some of the ideas about streamlining IRB organization and operations with the National Center for Advancing Translational Sciences and its Clinical and Translational Science Awards consortium. The broader research community could benefit.

## **Patient Safety and Clinical Quality Update**

*Laura M. Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality*

### ***Unannounced Joint Commission Survey Visit***

Ms. Lee said that on June 12, 2019, one Joint Commission surveyor—an engineer— visited the Clinical Center to assess compliance with the 2018 survey findings related to ligature risk. In addition, they reviewed compliance with utility standards related to appliances in a patient laundry (the presence of ground fault circuit interrupters). This issue was resolved immediately after the survey visit. Although this visit was unexpected, Ms. Lee said that she submits data regularly to the Joint Commission to document progress.

Two CCRHB members commented on the frequency of findings related to ligature risks in hospitals. Certain ligature-resistant door hinges are in great demand but short supply. Ms. Lee remarked on challenges in obtaining handles for Clinical Center furniture.

### ***OpenNotes™***

On July 12, 2019, the Clinical Center opened progress notes to patients through a partnership with OpenNotes, developed at Beth Israel Deaconess Medical Center, in keeping with an “international movement committed to spreading the availability of open visit notes and studying the effects.”

The Clinical Center was the second institution to provide real-time inpatient notes. OpenNotes helped structure the NIH program and met with staff who had some concerns about the new process – especially regarding the pediatric patient population. Ms. Lee discussed plans to study the effects of providing visit notes; efforts are under way to develop research questions in collaboration with OpenNotes.

Notes, including notes from consultations, are available on the patient portal. Laboratory test results are also available right away, except for some tests that need more explanation.

### ***Rapid Response Team***

Ms. Lee thanked the CCRHB for encouraging the NIH Clinical Center to allow for patient and family activation of the Rapid Response Team. She explained the plan to launch a 3-month pilot to study performance metrics, including the type of calls (are they appropriately urgent?), volume of calls, impact on ICU staffing, and patient perception.

### ***Code Blue Resources***

The scope of the Clinical Center's Code Blue team is much broader when compared with other hospitals. Staff perceived an increase in the activation of Code Blue responses for non-acute events during the period June 17–30, 2019. Eleven of the 14 events were assessed as appropriate or possibly appropriate, and three could have been managed otherwise. The Clinical Center Office of Patient Safety and Clinical Quality is considering potential solutions, including activation of a first aid response that would not require an ICU physician, expanded use of the Occupational Medical Service for non-acute events, and use of the NIH ambulance service to transport individuals who had non-Code Blue events.

### ***Performance Metrics***

Ms. Lee conducted a review of NIH performance metrics covering:

- **Patient perceptions:** The Clinical Center remains above benchmark averages established by the Centers for Medicare & Medicaid Services and the National Research Corporation for both inpatient and outpatient perceptions. ..
- **Infection control:** Hand hygiene is in 85% to 90% compliance range, continuing an upward trend since the first quarter of 2018.
- **Whole-house central line-associated bloodstream infection rate:** This metric has been precipitously declining since the third quarter of 2018. The ICU benchmark is 1.1 infections per catheter day, but the NIH ICU rate has remained at 0 since the first quarter of 2018.
- **ICU catheter-associated urinary tract infections:** No infections have occurred at NIH since the first quarter of 2018 with the exception of the third quarter of 2018, when the rate was 2.5 infections per 1,000 Foley catheter days, the national benchmark.
- **Catheter-associated urinary tract infections (CAUTI) in the surgical oncology service:** The CAUTI rate for this patient population was above the national benchmark for the 3<sup>rd</sup> and 4<sup>th</sup> quarters of 2018, due to the post-operative complexity of a small number of patients. In the 1<sup>st</sup> quarter of 2019 the rate was zero.
- **Surgical site infections:** Benchmarking is a challenge because of low surgery volume, The Clinical Center average rate is 1.3 infections per 100 procedures.
- **Nursing quality metrics:** The rate of inpatient falls (around 1.5 per 1,000 patient days) is well below the national benchmark of about 2.5. For falls with injury, the Clinical Center's average has remained below 0.26 for the past year.
- **Pressure injury prevalence:** The downward trend has continued since peaking at 5.5 patients among those surveyed having pressure injuries during Quarter 2 of 2018. The national mean is approximately 1.5. No Stage 3 or 4 pressure injuries have been detected in the past two quarters.
- **Barcode use:** The Clinical Center's compliance with bar code use has remained constant around 99%. The goal is 100%. Instances of noncompliance occur during emergencies or when specialty medicines that do not have barcodes are administered. Dr. Forese said that

if a product does not have a barcode, then it should not be included in this analysis, as there is no possibility for staff to scan the barcode.

- **Emergency response:** The Clinical Center’s data on Code Blue events have changed little over time. Ms. Lee said that Code Blue responses occur in about equal numbers for inpatients and outpatients. Only a few codes involve cardiac arrest; codes for stable and emergency events occur at about equal rates. In terms of patient disposition, most people remain on the unit or, in the case of employees, are transferred to the Occupational Medical Service. A smaller proportion is transferred to the ICU.
- **Rapid Response Team:** About equal numbers of patients remain on the unit or are transferred to the ICU after a rapid response is called.
- **Blood and blood product use:** The aim is to have a crossmatch-to-transfusion ratio of 2.0 or less, and the Clinical Center’s ratio is below 1.50. Monitoring of this metric ensures that blood does not go unused when it could be made available to another patient. In the past year, no anaphylactic reactions have occurred after transfusion, and the rate of nonhemolytic, febrile events remains below 0.2%. Hemolytic, septic, and transfusion-related acute lung injury events remain below 0.1%. The percentage of unacceptable blood bank specimens has remained consistently below the Clinical Center threshold of 3%.
- **Clinical documentation data:** The Clinical Center’s record (consistently below 10%) is better than the Joint Commission’s benchmark of less than 50% of records remaining delinquent 30 days after patient discharge. Ms. Lee pointed out that NIH tends to take more time than other institutions to close out records as investigators at times delay finalizing a record until they have all reports from all outside labs, autopsy results, and so forth. In response to a CCRHB request, Ms. Lee volunteered to get more information about this clinical documentation benchmark.
- **Accuracy of coding:** Clinical Center coding accuracy has consistently been in the 90% range. The Board requested information about how the coding is performed and how the audits are conducted.
- **Abbreviation use:** The use of abbreviations in clinical documentation is a source of error and mis-communication in healthcare. The NIH CC policy is to avoid the use of unapproved abbreviations. Adherence to this policy in the Clinical Center has consistently remained in the 95% range; the goal is 100%.
- **Employee safety measures:** Ms. Lee said that NIH Clinical Center considers “days away from work” as, perhaps, the most important metric presented. Most occupational injuries consist of twists and sprains. Dr. Shannon said that the metrics reflect impressive continuous improvement, but he noted that it was difficult to compare these metrics to the industry as a whole. He suggested calculating the total reported incident rate based on the number of Clinical Center employees. For example, based on an estimate of 2,000 Clinical Center employees and 34 total reportable cases, the rate would be 1.7, which compares very favorably with the national average for hospitals of 4.2. Dr. Shannon

suggested focusing on reduction of ergonomic injuries. Employee safety metrics demonstrate a commitment to employees per Aim 4 of the strategic plan.

### ***Follow-Up Items***

- For future presentations, the CCRHB asked that data on barcode use exclude instances attributed to specialty medicines that do not have barcodes.
- Ms. Lee will clarify for the CCRHB whether the clinical documentation benchmark is self-imposed or required by the Joint Commission.
- Ms. Lee volunteered to find out which NIH entity or personnel conducts the audit for accuracy of coding.
- For employee safety events, the CCRHB asked that Ms. Lee report data as rates instead of numeric counts to facilitate comparisons to other institutions.

### **Closing Statement and Adjournment**

*Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian; and Chair, CCRHB*

Dr. Forese closed the 13th meeting of the CCRHB by thanking the presenters and the CCRHB members. The presentations gave the Board a sense of progress with Clinical Center facilities, the strategic planning process, and patient safety.

The next face-to-face meeting of the CCRHB is scheduled for October 18, 2019.

Dr. Forese adjourned the meeting at 1:47 p.m.

/ Laura Forese /

Laura Forese, M.D., M.P.H.

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, NewYork-Presbyterian

/ Lawrence A. Tabak /

Lawrence A. Tabak, D.D.S., Ph.D.

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/ Francis S. Collins /

Francis S. Collins, M.D., Ph.D.

*Ex Officio* Member, NIH Clinical Center Research Hospital Board

Director, NIH

## **Abbreviations and Acronyms**

ADC	average daily census
BAS	building automation system
CCGB	Clinical Center Governing Board
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CGMP	Current Good Manufacturing Practice
CRC	Clinical Research Center
DLM	Department of Laboratory Medicine
FDA	U.S. Food and Drug Administration
FIH	first-in-human
FMEA	failure modes and effects analysis
FY	fiscal year
HHS	U.S. Department of Health and Human Services
HRPP	Human Research Protection Program
HSCT	hematopoietic stem cell transplant

ICs	Institutes and Centers
ICU	intensive care unit
IRB	institutional review board
IRP	Intramural Research Program
IVAU	intravenous admixture unit
MEC	Medical Executive Committee
NCI	National Cancer Institute
NEF	Nonrecurring Expenses Fund
NHGRI	National Human Genome Research Institute
NICHHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
OHSRP	Office of Human Subjects Research Protections
PAG	Patient Advisory Group
SCSU	Special Clinical Studies Unit
SRLM	Surgery, Radiology, and Laboratory Medicine [building]

TIL                      tumor-infiltrating lymphocyte

USP                      U.S. Pharmacopeia