

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

# Nineteenth Meeting of the Clinical Center Research Hospital Board

October 15, 2021

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## **Clinical Center Research Hospital Board**

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, New York–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

Ruth Williams-Brinkley, M.S.N.-Adm., President, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

Norvell V. Coots, M.D., President and Chief Executive Officer, Holy Cross Health (*ad hoc* member)

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

Steven I. Goldstein, M.H.A., President and Chief Executive Officer, University of Rochester Medical Center

William Hait, M.D., Ph.D., Global Head of External Innovation, Johnson & Johnson (*ad hoc* member)

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

Richard P. Shannon, M.D., Chief Quality Officer, Duke Health

\*Absent

## **Executive Summary**

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 19th meeting via videoconference on October 15, 2021. The meeting was webcast live and open to the public. A [video recording of the meeting](#) is available online.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, New York–Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:00 a.m. ET. All Board members were present. Dr. Forese noted that this would be the final meeting attended by Francis Collins, M.D., Ph.D., NIH Director, who is retiring soon. The Board looks forward to working with Dr. Collins’s successor and with an acting director, should one be appointed.

Dr. Collins thanked the Board for its service to the Clinical Center, especially Dr. Forese, who has proven that she is a skillful leader with strong experience and great vision. He noted that he has served as NIH director for an unprecedented 12 years through three presidential administrations. Dr. Collins appointed 20 of the current 27 NIH Institute and Center directors. Dr. Collins says he has advocated for Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, and Executive Director, CCRHB, to step in as acting director.

Dr. Collins took special pride in NIH’s role in creating effective, safe vaccines for coronavirus disease 2019 (COVID-19), which have spared untold lives and suffering during this pandemic. NIH also led the way with research that supported the development of monoclonal antibodies as well as the antiviral drug remdesivir and more recently molnupiravir, an oral agent that appears to reduce hospitalization rates by as much as half. Dr. Collins cautioned that although case rates are down somewhat, this is no time for complacency as winter approaches. The nation must also better prepare for future pandemics. In closing, Dr. Collins thanked the CCRHB for asking hard questions, advising NIH, and patting people on the back when they do the right thing to keep patients and staff safe.

James Gilman, M.D., Chief Executive Officer, NIH Clinical Center, announced several key staffing changes, including the hiring of the chief of the Office of Patient Safety and Clinical Quality, a Clinical Center epidemiologist, and the chief medical officer. Searches are ongoing for several key positions, including those of chief nurse officer, Clinical Center chief of materials management and environmental services, director of education and training, and executive director of the Graduate Medical Education training program.

Dr. Gilman noted that the hospital’s average daily census hovers around 80, about two-thirds of the Clinical Center’s three-year average before the pandemic. Telehealth appointments peaked in March 2021 and have declined somewhat as people have started returning to the Clinical Center for study visits.

In a separate presentation, Dr. Gilman updated the board on the outcomes of the Joint Commission survey conducted in late August 2021. The surveyors had high praise for staff engagement and the Clinical Center’s culture of safety. However, a few problems were uncovered, including a health and safety finding related to high-level disinfection and sterilization, but the Clinical Center rapidly resolved the issue and passed a follow-up abatement survey on September 22.

Dr. Gilman updated the Board on screening and testing of staff for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In keeping with the federal vaccine mandate, NIH staff must be vaccinated by November 22, 2021, and contractors must be vaccinated by December 8, 2021.

David Lang, M.D., M.P.H., Director, NIH Clinical Center Office of Patient Safety and Clinical Quality presented metrics from the Clinical and Safety Performance Metrics Executive Dashboard, which was distributed to the CCRHB members before the meeting. The document is online ([https://www.ccrhb.od.nih.gov/documents/10152021\\_Executive\\_Dashboard.pdf](https://www.ccrhb.od.nih.gov/documents/10152021_Executive_Dashboard.pdf)). The metrics indicate consistent strong performance in infection control, nursing care, and employee safety.

Barbara A. Jordan, D.N.P., RN, NEA-BC, Acting Chief Nurse Officer, reported that a year has passed since the Clinical Center embarked on its Magnet® journey. Organizational benefits have already accrued to the Clinical Center in terms of resources, education, networking opportunities, and meetings with a senior ANCC Magnet® analyst. Dr. Jordan said that the goal is to submit the Magnet® recognition application in May 2022 and the documents by October 2023.

Ann Cohen-Berger, M.D., M.S.N., Chief of Pain and Palliative Care Service, and Senior Research Clinician, explained that the Clinical Center's hospice unit grew out of the missions of two programs—the Pain and Palliative Care service and the Spiritual Care Department—both of which focus on the physical, spiritual, psychological, and social needs of Clinical Center patients at the end of life. On any given day, the team sees about a quarter of all inpatients. Since July 2018, 54 patients ages 29 to 92 years have been served by hospice care. Training opportunities are available through a fellowship program, and research is an important component of the palliative care and hospice programs.

According to John M. Pollack, M.Div., BCC, Chief, Spiritual Care Department, the Spiritual Care Department is dedicated to individualized care. To goal is to serve people with a system of spiritual care, rooted in compassion. All patients and their families are seen within 24 hours of admission to hospice. The team also provides spiritual care for Clinical Center hospice nurses and other hospice caregivers.

The meeting concluded with a presentation by Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, who discussed the mechanisms that support interactions between NIH and the pharmaceutical industry. The CCRHB had requested a presentation on this topic during an earlier meeting.

The next meeting of the Board will occur on April 1, 2022.

# Meeting Summary

## Friday, October 15, 2021

### Welcome and Board Chair's Overview

*Laura Forese, M.D., M.P.H., New York–Presbyterian, and Hospital Board Chair*

Dr. Forese called the meeting to order at 9:00 a.m. ET and checked attendance, noting that the impending retirement of Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH), means that this was his final Clinical Center Research Hospital Board (CCRHB) meeting.

Dr. Forese thanked Dr. Collins for all he has done for science and humankind. He is leaving NIH in excellent shape. The Board looks forward to working with an acting director and other NIH leaders until Dr. Collins's successor is appointed.

### NIH Director's Remarks

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

Dr. Collins thanked the Board for guiding the Clinical Center. In particular, he acknowledged Dr. Forese, who has skillfully led the CCRHB with her experience and vision.

#### *Farewell*

Dr. Collins plans to step down by the end of 2021. When President Joe Biden asked Dr. Collins to remain as NIH director, Dr. Collins responded by saying he would stay on for a time because of the pandemic, but he also said that scientific organizations need a new vision from time to time. He said that leading the NIH—a “ship of discovery”—for more than 12 years through three administrations has been an amazing opportunity. Dr. Collins appointed 20 of the leaders of the NIH's 27 Institutes and Centers (ICs).

Dr. Collins has full confidence in Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; and Executive Director, CCRHB, and supports his appointment as acting NIH director. Decisions about an acting director are being handled through the White House personnel process, but Dr. Collins is optimistic that an announcement will be forthcoming soon.

Dr. Collins expressed pride in NIH's role in developing vaccines, treatments, and tests for coronavirus disease 2019 (COVID-19). Dr. Collins noted that an advisory panel of the U.S. Food and Drug Administration (FDA) will be discussing an NIH study on mix-and-match vaccine booster strategies. He said that people who received the Johnson & Johnson/Janssen vaccine should probably get vaccinated with an mRNA vaccine as well. However, all three vaccines are remarkably safe and effective. It is noteworthy that a COVID-19 vaccine had achieved FDA emergency authorization within just 11 months. Operation Warp Speed led to development of six vaccine candidates. Dr. Collins said that the mRNA platform has proven to be a highly effective and fast platform for implementing vaccine programs. He recommended preparing now for future outbreaks by capitalizing on the mRNA platform to start designing and Phase I testing vaccines for the 20 most likely emergent infections.

The Rapid Acceleration of Diagnostics (RADx) program has supported the development of 32 new technologies for clinical application (e.g., COVID-19 home test kits). An NIH-supported pilot project is distributing home test kits in selected communities to evaluate the effects of making tests broadly available. Discussions about the possibility of test distribution on a national level are underway.

After retiring as director, Dr. Collins plans to focus more on the research going on in his National Human Genome Research Institute laboratory, where about 10 people work. They are investigating hereditary factors in type 2 diabetes, focusing mainly on epigenetics using stem cells and single-cell biology. They are also investigating Hutchinson-Gilford progeria syndrome, a very rare, multisystemic disease that causes premature aging and death in children. The research team is working on new treatments using a clustered regularly interspaced short palindromic repeats (CRISPR) technique in a mouse model of progeria. Preliminary results suggest that a single infusion of an adeno-associated virus (AAV)-driven gene editor may be able to ameliorate cardiovascular features of the disease by fixing a single nucleotide. Dr. Collins hopes to bring this regimen to a clinical trial. The gene-editing approach may open new opportunities for the 7,000 genetic diseases that lack a treatment.

In retirement, Dr. Collins hopes to pursue writing and explore mini-sabbatical experiences at other institutions.

Dr. Collins closed by acknowledging the Board's contributions to NIH. The CCRHB has transformed the way NIH staff think about patient care at the Clinical Center. He encouraged the CCRHB to continue asking hard questions, advising, and patting people on the back when they do the right things.

### ***Discussion***

Richard P. Shannon, M.D., congratulated Dr. Collins on his impending retirement and thanked him for graciously acknowledging the Board's contributions. He added that Dr. Collins has taught him much about what leadership is and that he has never met anyone who is a better communicator around complex issues and who has maintained such equanimity over enormous ups and downs. Through Dr. Collins's example, Dr. Shannon learned the critical importance of communicating in a way that touches people.

As a patient advocate, Ellen Berty thanked Dr. Collins on behalf of all the patients for whom she speaks. She appreciates his concern for patients and his excellent leadership.

Ruth Williams-Brinkley, M.S.N.-Adm., echoed Dr. Shannon's remarks, praising Dr. Collins for being steady, calm, and reliable. She also appreciates his whimsical, joyful love of music, noting that the videos of Dr. Collins and his band were enjoyable and revealed his breadth of interests.

Stephanie Reel, M.B.A., said she recently reread Dr. Collins's book *The Language of God: A Scientist Presents Evidence for Belief* and was touched by the connections drawn between science and faith. She hopes that Dr. Collins will have an opportunity to continue writing. Dr. Collins said that book needs a new edition; although the faith has not changed, the science has evolved.

## **NIH Clinical Center Chief Executive Officer Update**

*James Gilman, M.D., Chief Executive Officer, NIH Clinical Center*

Dr. Gilman thanked Norvell V. Coots, M.D., for joining the Board noting that they had worked together in the military for approximately 20 years, and now more Trinity Health partnerships with the Clinical Center can be explored.

### ***Staffing Changes***

Dr. Gilman announced that some key positions have been filled:

- David Lang, M.D., is now the Chief of the Clinical Center Office of Patient Safety and Clinical Quality. Previously, he served as an essential clinician for his contributions to expanding the pediatrics program at the Clinical Center. Dr. Lang stepped into his new role just a day before the Joint Commission survey.
- Brooke Decker, M.D., accepted the position of Clinical Center Hospital Epidemiologist and Chief of the NIH Clinical Center Hospital Epidemiology Service. She approaches problems more from an environmental than a genetics standpoint and is an expert in hospital water systems.
- Colleen Hadigan, M.D., M.P.H., accepted the position of Clinical Center Chief Medical Officer (CMO). She served as the acting CMO for the past year.

Dr. Gilman said that NIH is searching for candidates to fill other important roles in the Clinical Center, including those of Chief Nurse Officer, Chief, Materials Management and Environmental Services, Director of Medical Education and Training, and Executive Director of the Graduate Medical Education program.

### ***Awards***

Dr. Gilman mentioned several recent and upcoming recognitions of NIH Clinical Center employees:

- One hundred twenty-nine Clinical Center employees (five individuals and 24 groups) received 2021 NIH Director's Awards.
- The Clinical Center Director's Awards will be given out at a virtual ceremony on December 17, 2021. Approximately nine hundred staff received awards in 2020, with large groups in a new category for "Making an Impact Category: COVID-19". 700 staff are being considered for 2021 awards.
- Five employees will be recognized by Dr. Collins for their clinical and administrative contributions during an upcoming quarterly town hall meeting.
- The American Health Information Management Association recognized the Clinical Center's health information team with its Grace Award for fostering a culture of innovation, especially around social determinants of health data and health disparities. Dr. Gilman explained that this award reflects the strong relationship between teams focusing on informatics and health information, which will be combined into a single

department to support full integration of clinical and research information to an extent not realized at any other health institution.

### ***New Electronic Consenting System***

Dr. Gilman explained the new iMedConsent systems, which allows signed consents to be uploaded to the clinical research system immediately after they are finalized. This application will help streamline documentation and filing after consent discussions are done. The hope is that the initial study visit will be more productive if consent is handled in advance of the appointment.

### ***Average Daily Census (ADC)***

The ADC in 2021 has remained stable around 80, about two-thirds of the average for the three years before the pandemic. The Clinical Center was very busy in the first quarter of calendar year 2020, but the ADC declined sharply thereafter when the pandemic shut down many activities.

Telehealth appointments peaked in March 2021 at about 1,200 per month and have since declined to around 750, most likely because more people are now being seen in person for imaging studies and clinical evaluation.

Outpatient visits are up 10% over fiscal year (FY) 2020.

### ***Emergency Management Exercises***

A spring exercise for CC staff and stakeholders was conducted successfully. Lessons learned included the following:

- Increase redundancy in messaging.
- Review and improve Clinical Center emergency leadership role sheets.
- Refine virtual platforms with positions required on site versus virtual positions.

A fall exercise is planned for November 2021 to test refinements on a larger scale by including the National Cancer Institute (NCI) and the Center for Information Technology. The NIH Division of Fire and Rescue Services, the NIH police, Suburban Hospital, Walter Reed National Military Medical Center (WRNMMC), and the National Library of Medicine will also be involved. The fall exercise will be larger than the one in June and will better test the community's emergency-response systems.

### ***Pediatrics at the Clinical Center***

Dr. Gilman said Lori Wiener, Ph.D., DCSW, LCSW-C, of the Pediatric Oncology Branch, proposed the idea of the NIH Clinical Center Treasure Tour, an interactive video game to help familiarize children with the Clinical Center and perhaps make their experience less intimidating (<https://clinicalcenter.nih.gov/treasuretour>). Much of the visual information in the app came from staff with the Clinical Center's Office of Communications and Media Relations. Dr. Wiener built in a feedback effort for the app's rollout to see whether people find it beneficial. Ms. Berty reported that she has played the game and enjoyed it.

### ***COVID-19 Screening, Testing, and Vaccination of Building 10 Staff***

Dr. Gilman reported that as of October 5, 2021, nearly 2 million people have been screened for COVID-19 before entering Building 10. The daily maximum was nearly 6,400. The Clinical Center continues to offer asymptomatic testing; more than 130,000 tests have been completed on 13,390 employees. The testing has returned few positives, demonstrating that the Clinical Center is a safe place to work in terms of potential exposure to COVID-19. In addition, there has been no documented transmission from staff members to patients.

Per the federal vaccine mandate, all employees must be fully vaccinated by November 22, 2021, and contractors have a deadline of December 8. There are exemptions for medical and religious reasons; NIH leaders are working out a way to adjudicate exemptions. Dr. Gilman was interested in learning how other medical facilities are dealing with vaccine exemptions.

### ***Five Years Ago***

Dr. Gilman recalled being sworn in as the Clinical Center's chief executive officer (CEO) on January 9, 2017. Four days later, he presented to the CCRHB for the first time.

Dr. Gilman recounted numerous successes during his tenure as CEO:

- Creation of the Office of Research Support and Compliance
- Creation of the Patient Safety, Clinical Practice, and Quality Committee
- Integration of failure mode and effects analysis into the culture
- Clinical Center construction in collaboration with the NIH Office of Research Facilities
- Expansion of the Center for Cellular Engineering
- Major renovations to the inpatient and outpatient pharmacies
- Planning of Surgery, Radiology, and Laboratory Medicine construction, slated to occur 2022–2028
- Establishment of the Behavioral Emergency Response Team and the Anti-Harassment Response Team
- Improvements to the electronic health record system, enhanced telemedicine, and the electronic intensive care unit (ICU) telemedicine system
- Expansion of the pediatrics program with a new observation unit, including hiring of a pediatric anesthesiologist and pediatric hospitalists
- Enhanced collaborations with other community medical facilities, WRNMMC, Children's National Hospital, Suburban Hospital, and the Maryland Institute for Emergency Medical Services Systems
- A collaborative, successful pandemic response thus far
- Progress on the journey to high reliability

Dr. Gilman said that these accomplishments were possible only with the support of NIH leaders and staff, but he acknowledged that opportunities for improvement remain. In closing, Dr. Gilman expressed gratitude to Dr. Collins for his longstanding support during these past 5 years and wished him Godspeed.

## *Discussion*

Ms. Reel recalled a conference convened by the Joint Commission Clinical Research Forum in 2006 on the possibility of integrating research and care in academic medical centers. Most of the conference attendees thought that such an integration was neither possible nor necessary. In the years since, the value of information and true integration in generating meaningful information has been appreciated. Patients and research participants are now front and center and the push toward precision medicine brings together patients, clinicians, and researchers.

Referring to vaccine mandates, William Hait, M.D., Ph.D., said that at Johnson & Johnson, vaccination has generally been accepted, although some people have been holding out. He asked whether NIH has come up with approaches to overcome vaccine hesitancy. Dr. Gilman said that NIH does not have a clear solution. He recommended listening to people, but a hard line must be drawn to protect patients and staff. The bar for getting an exemption has to be higher than that for annual influenza vaccinations. Dr. Collins said that misinformation and disinformation have made many people feel fearful and confused about COVID-19 vaccines. Mandates may be a useful tool. Dr. Collins said it is irrational and frustrating that people rely more on social media for information than on scientific evidence. He predicted that NIH will have to release a few staff who are unwilling to get vaccinated.

Dr. Forese said that New York–Presbyterian Hospital was the first hospital in New York to announce a deadline for employee vaccination. Vaccination is a condition of employment at the hospital. One hundred fifty people qualified for exemptions through a process that included adjudication by a panel and an appeals process. Fewer than 200 people left the organization. People usually waited until the last minute to decide whether to get vaccinated or lose their job.

Duke Health has 27,000 employees, according to Dr. Shannon. He said that more people sought religious exemptions than has been the case with influenza vaccinations. In the end, 11 Duke employees were let go.

Dr. Shannon asked whether the Clinical Center has been experiencing challenges with hiring or higher turnover. Dr. Gilman said that starting about a year ago, the Clinical Center has been more fully staffed than at any time since he arrived at NIH. The uptick in hiring started in late 2019 and continued into FY 2020. The reasons for this trend are complicated, but one likely reason is that the Clinical Center has had fewer COVID-19 cases than other hospitals. Risk has been lower because there is no emergency department. These factors likely made work at the Clinical Center appealing to many staff. Also, some staff delayed retirement because they were able to work remotely and many activities that retired people enjoy, such as travel, were not possible due to the pandemic. Now more resignations are occurring, particularly in the Department of Laboratory Medicine. More tests are being sent to outside labs as new people are being trained.

Barbara A. Jordan, D.N.P., RN, NEA-BC, acting chief nurse officer, said that another challenge relates to lucrative contracts in areas affected by COVID-19; the federal government cannot compete with high hourly rates being paid to contract staff by other organizations. Dr. Coots said that some institutions are using funds received under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, but not originally allocated, to pay for the staffing deficit, because contract labor is up to \$225 per hour. It seems to be an unending cycle, but the Maryland

Hospital Association is trying to resolve the situation during the middle of this national crisis, perhaps by capping costs.

Ms. Williams-Brinkley said that the Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., did not take CARES dollars, but it still faces challenges affecting staffing, including a vaccine mandate, people leaving their jobs, and a strike. She wishes closing for a day to give people a mental health break were possible. She suggested that solutions may lie in new models of care.

Steven I. Goldstein, M.H.A., noted that vaccination has been highly politicized in Rochester, New York. Every day, 200 to 300 protestors gather around the medical center, disrupting operations. New York State's courts are taking up the question of vaccine mandates. The Department of Health is not recognizing religious exemptions. Employees have the option of being tested weekly, but some say that they will not abide by that requirement. Staff who refuse vaccination or testing will be terminated. Many traveling nurses are being brought in, but nursing homes are being affected. Twenty-six nursing homes are not accepting new patients because of staffing shortages, particularly of certified nursing assistants and licensed practical nurses. This is affecting the continuum of care.

## **Report: Joint Commission Triennial Accreditation Survey Visit**

*James Gilman, M.D., Chief Executive Officer, NIH Clinical Center*

Dr. Gilman announced that the three-day Joint Commission survey occurred at the end of August. The team that conducted the survey included a physician, a nurse, and an engineer. The Clinical Center failed to meet 18 standards. Dr. Gilman learned through informal channels that the average number of standards cited in most contemporary surveys is between 45 and 60. The team had high praise for staff engagement and the Clinical Center's culture of safety.

Referring to the Survey Analysis for Evaluating Risk™ (SAFER) matrix, Dr. Gilman noted that an environmental care standard was not met. Quality control logs for magnetic resonance imaging equipment were missing some entries, likely associated with supervisor's inability to be onsite early in the pandemic.

Dr. Gilman also noted that a standard related to provision of care was not met. The hospital uses written criteria to identify patients who may be victims of assault, abuse, and neglect. In the past, it was sufficient to have a written policy and tool for inpatients, but these must now be implemented in all outpatient venues as well. No problem was identified during the last survey, so staff had assumed that the Clinical Center met this standard. Dr. Lang is now creating a new policy to ensure compliance with the standard.

The survey revealed an imminent threat to health and safety related to high-level disinfection and sterilization, but the Clinical Center rapidly resolved the issue as reported in a follow-up abatement survey on September 22. The surveyors found pitted instruments and instruments with evidence of oxidation that should have been discarded. Several clinics, not just one, were affected, raising questions about training and leadership standards. To abate the problem, staff swept the entire Clinical Center for instruments and sterile supplies. Some instruments were discarded, and others were set aside for refurbishment.

This activity was followed by intensive education and training to prevent such problems in the future. Staff were coached to keep only a 2- or 3-week supply on hand instead of stockpiling instruments. Follow-up visits were made to clinics and procedure areas where issues were noted. Additional abatement activities are planned:

- Work on clean utility rooms.
- Move Sterile Processing to its new home in the B1 area.
- Decide where (organizationally) Sterile Processing belongs. Materials Management may not be the right place. The Clinical Center Nursing Department may be an option.
- Reassess how the Clinical Center handles annual focused standards assessments (FSAs), since this issue was not identified during the FSA.

Dr. Gilman assumed accountability reporting overconfidence by leadership in centralization of all high-level disinfection and sterilization four years ago. That action did not account for stockpiling supplies. Because there are no other hospitals like the Clinical Center, the practice has been to rely on internal staff for conducting FSAs. Clearly, a more orthogonal view is needed for FSAs. Dr. Lang is coming up with a plan.

Dr. Gilman reported that he contacted Dr. Tabak, Michael Gottesman, M.D., deputy director of intramural research, and Dr. Forese immediately after the outbrief. Although they had concerns about the survey outcomes, they offered reassurance and offers of support.

### ***Discussion***

Ms. Reel said that mock survey rehearsals are the best way to catch problems before surveys.. The Joint Commission surveyors often comment that they do not survey any other place like the Clinical Center. That said, the Clinical Center does conduct mock exercises for monitoring safety and environmental care. For 25 years, the Clinical Center has engaged a particular consultant who wrote the Environment of Care chapter to help prepare for surveys, but mock surveyors have not been used for the FSA process. Ms. Williams-Brinkley pointed out another benefit of mock surveyors: They bring in ideas from other places. Dr. Gilman observed that the pandemic cut down the number of people doing mock surveys.

Dr. Gilman said that the Clinical Center focused on mitigating ligature risks, but the survey revealed no problems in this regard.

Dr. Forese underscored the importance of looking at the full picture because many findings were highly positive. She praised the Clinical Center staff and leaders for working together to fix the identified issues quickly.

## **Clinical and Safety Performance Metrics**

*David Lang, M.D., M.P.H., Director, NIH Clinical Center Office of Patient Safety and Clinical Quality*

The *Clinical and Safety Performance Metrics Executive Dashboard* was distributed to the CCRHB members before the meeting. The document is also available online ([https://www.ccrhb.od.nih.gov/documents/10152021\\_Executive\\_Dashboard.pdf](https://www.ccrhb.od.nih.gov/documents/10152021_Executive_Dashboard.pdf)).

## ***Infection Control***

Dr. Lang reported on several metrics related to infection control:

- The hand hygiene metric is consistently between 90% and 95%. The metric is based on observations, not self-reports. Trained staff throughout the organization conduct “secret shopper” observations.
- Numbers of central-line–associated bloodstream infections (CLABSIs) are consistently low in the Clinical Center. Currently, the rate is 0.25 per 1,000 catheter days, but it has not exceeded 1.3 since the second quarter of 2020. The rate is normalized to 1,000 catheter days, so the statistic is unaffected by the ADC. CLABSI rates in the ICU are similarly low and are judged against the CDC National Healthcare Safety Network’s (NHSN) benchmark of 1.1.
- Numbers of ICU catheter-associated urinary tract infections (CAUTIs) vary, but the trend has declined and is approaching the national baseline of 2.7. The CAUTI rate in surgical oncology recently spiked at nearly 4.5. The NHSN benchmark is 1.3. The Patient Safety and Clinical Quality team looks into the numbers to discern the reasons behind the infections.
- Surgical site infection rates vary based on types of procedures. The rate has increased over the past two quarters; the current rate is 3 per 100 procedures. The benchmark is about 1.8. The team is investigating.

## ***Nursing Quality Metrics***

Dr. Lang reviewed metrics related to nursing quality:

- The inpatient fall rate is consistently below the benchmark of 2.8 and is normalized to 1,000 patient days. The most recently quarterly rate was 1.0, and the rate of inpatient falls with injury was about half that.
- Pressure injury prevalence has varied above and below the national benchmark, but it is currently close to the national benchmark. No stage 3 or 4 pressure injuries have occurred in the past year.
- The goal of the barcoding system is to eliminate errors in medication administration. Barcode use is consistently 99%, but barcoding is not feasible in a few areas of the Clinical Center.

## ***Emergency Response***

Dr. Lang explained that a Code Blue may be called in a variety of circumstances and for staff and visitors in addition to patients. Over the past year, a total of 200 Code Blues were called; about half were for inpatients, and the remainder were for outpatients, employees, and visitors. Brain codes ensure that patients can rapidly undergo stroke evaluation and be transferred to a stroke center. Most codes in the Clinical Center are for acute emergencies and stable events, such as falls.

Dr. Lang explained that after a code response, about a quarter to a third of patients are transferred to the ICU, a similar proportion are transferred to an outside hospital, and another quarter remain on the same unit. Fewer people are released from the Clinical Center or die.

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

According to Dr. Lang, in the past year, the Clinical Center logged about 95 calls for the Rapid Response team. After a rapid response, about half of patients remain on the same unit, a quarter are transferred to the ICU, and the remainder are transferred to another unit or elsewhere. So far, no patients or families have utilized the Rapid Response system.

### ***Blood and Blood Product Use***

Dr. Lang explained that the Clinical Center aims for a crossmatch-to-transfusion ratio of 2 or less to ensure that blood is not held unused in reserve when it could be available for another patient. The ratio has remained stable and consistently below the goal.

The percentage of transfusions associated with transfusion reactions is very low, at less than 0.5%. Most are either febrile and nonhemolytic or classified as “other.” No hemolytic, septic, or anaphylactoid reactions have occurred.

Blood bank specimens are used for crossmatching. The proportion of specimens that are unacceptable due to labeling problems or hemolysis is currently 1%, well below the Clinical Center threshold of 3%. Unacceptable specimens are discarded, and new samples are drawn.

### ***Clinical Documentation***

Dr. Lang said that the Clinical Center consistently achieves 90% patient record completion within 30 days after discharge. The Joint Commission benchmark is 50% completion within 30 days.

“Agent for” orders countersignature compliance has been consistently in the 90% to 95% range.

The Clinical Center aims to avoid all use of abbreviations. “Do not use” abbreviation adherence is around 96%.

The Clinical Center aims for at least 90% accuracy of record coding. The accuracy rate has consistently remained at 95%.

### ***Employee Safety***

Dr. Lang reported that over the past year, the number of total recordable cases (TRC) peaked at 24 during the first quarter of 2021. Of these, 15 resulted in days away from work, restricted, or transferred (DART). For the most recent period, TRC declined to 10 and DART declined to 5.

### ***Discussion***

Regarding employees’ psychological injury and burnout, Dr. Forese asked how these statistics could be tracked at the Clinical Center. Dr. Lang said he plans to rely on reports from colleagues, medical staff, and nursing colleagues. Dr. Jordan added that other metrics, such as wellness program and sick leave utilization, would be informative. She is also looking at Joint Commission standards on violence in the workplace and ways to ensure that people are aware of resources available to them.

Ann Cohen-Berger, M.D., M.S.N., said that the Clinical Center has copious well-being resources available. An effort is underway to coordinate them in a single package. Currently, there is no system for tracking utilization numbers for staff, but this is being done for Graduate Medical Education fellows.

Dr. Shannon said he is reassured to see low rates of hospital-acquired infections, because so many Clinical Center patients are immunocompromised. Because the numbers are small, the team has an opportunity to see where problems lie with catheter manipulation, for example, and learn from these rare events. Dr. Lang agreed, saying that each event is examined from nursing and hospital epidemiology perspectives. Dr. Gilman said that detailed analyses have not revealed any patterns or trends; the events tend to be one-offs. Dr. Shannon was interested in comparing the results of those analyses with the experiences at other institutions.

Dr. Shannon suggested comparing Clinical Center data on employee injuries to industry benchmarks (e.g., published DART data). Dr. Lang supported this idea.

### ***Action Items***

- The Board recommended benchmarking against published standards for work-related employee injuries (e.g., DART).
- Because the Clinical Center analyzes each hospital-acquired infection in detail, the Board recommended exploring the possibility of sharing and comparing information with other institutions.

## **New Clinical Center Patient Survey**

*Colleen Hadigan, M.D., Chief Medical Officer, NIH Clinical Center*

Dr. Hadigan said that between 2009 and 2020, the Clinical Center used the NRC Health instrument for patient experience surveys. These were pen-and-paper surveys, and patients received no more than one survey per year.

### ***Survey Instrument Selection***

When the NRC Health contract was up for renewal in 2020, the Clinical Center investigated options that would offer electronic survey capability, the ability to sample additional services (e.g., surgery, procedure services), foreign language versions, Magnet<sup>®</sup>-compliant methodology, and dynamic, real-time survey capacity for embedded targeted sets. Ultimately, the Press Ganey Patient Survey was selected.

Key features of the Press Ganey survey include the following:

- Surveys are shorter and less burdensome.
- Surveys go out closer to the patient's visit completion date.
- Up to four surveys per year are sent by email to all patients with NIH Clinical Center encounters.
- Additional care areas are covered by the survey, including the operating room, apheresis, radiation oncology, and behavioral health. (Behavior health surveys are paper-based.)
- The instrument accommodates more free-text responses or comments.

The new survey launched on April 1, 2021. Reach-back surveys were sent for all encounters that occurred between January 1 and April 1, 2021. Respondents have the option of identifying themselves.

One challenge has been creating a systematic approach to review the many comments. The team is doing a weekly data pull of comments, which are being reviewed by staff of the Office of Patient Safety, the Patient Representative, the Health Information Management Department, and Dr. Hadigan as Chief Medical Officer to determine which items need follow-up.

### ***Some Early Findings***

Dr. Hadigan reported that nearly 13,000 e-surveys have been sent out as of September 30. The return rate is 23.1%. Now that data have been collected over three quarters, the team has begun generating quarterly reports.

Dr. Hadigan presented an example of a survey output. For inpatient services over the past three quarters, the Clinical Center ranked in the 89th to 98th percentile relative to the Press Ganey database. Furthermore, between 71% and 77% were top-box responses. For outpatient medical services, top-box responses made up 80% to 85% of responses over the past three quarters. For Radiation Oncology and Apheresis, the percentage of top-box responses ranged from 87% to 93%.

### ***Looking Ahead***

Dr. Hadigan listed several goals, including finalizing the process for reviewing comments, further training of stakeholders and users on report generation, provision of detailed data review for specific clinics or staff, reduction in the number of undeliverable emails with survey links, and conversion of behavioral health surveys to an electronic format.

Dr. Hadigan pointed out that some people receive the wrong type of survey (telehealth versus in-person visit), so this problem is also being corrected.

### ***Discussion***

Dr. Reel inquired about gathering data from feedback from patients prior to discharge. Is there a way to assimilate these anecdotal data, since people who already voiced concerns while they were in the Clinical Center may be less likely to complete surveys? Dr. Hadigan said that real-time feedback would not be captured systematically. The e-survey system allows anonymity, which may encourage respondents to be more candid. Comparing feedback given while in the Clinical Center with e-survey responses might be possible, but linking the data would not. Dr. Gilman added that the comments given in the Clinical Center are not collected in a systematic way, but the Patient Representative may receive the feedback and report back during monthly meetings. He said that the team reviews each request for assistance that the Patient Representative issues. There is an effort to look for trends, but the information is not collected or analyzed in a systematic way. Dr. Hadigan said that the hope is to aggregate data and give feedback to relevant services.

Dr. Shannon asked about plans to track racial/ethnic differences in response rates and in responses. He added that the high scores in radiation oncology and apheresis service areas likely reflect some best practices. How can these be captured and replicated in other areas of care? Dr.

Hadigan said that the data will certainly be used to export best practices. The team is studying database tools that would identify questions that are driving results.

### ***Action Items***

- The Board requested a presentation by [CAPT Antoinette L. Jones, M.S.O.D., RN, Patient Representative](#), NIH Clinical Center, during its next meeting.
- Dr. Hadigan volunteered to work with a Board member whose spouse did not receive a survey request after an inpatient stay in the Clinical Center.

## **Update: American Nurses Credentialing Center (ANCC) Magnet® Journey**

*Barbara A. Jordan, D.N.P., RN, NEA-BC, Acting Chief Nurse Officer, NIH Clinical Center*

Dr. Jordan said that a year has passed since the Clinical Center embarked on its Magnet® journey. Organizational benefits have already accrued to the Clinical Center in terms of resources, education, networking opportunities with other Magnet® organizations, and monthly meetings with a senior ANCC Magnet® analyst. The analyst provides insights to guide the development of the Clinical Center's documents.

Dr. Jordan said that the goal is to submit the Magnet® recognition application in May 2022 and the documents by October 2023.

### ***Magnet® Consultant***

Dr. Jordan explained that the Clinical Center arranged for the services of an independent Magnet® consultant in September 2021. Services include a Magnet® readiness assessment, gap analysis, Magnet® writers' seminar, aid with document preparation and submission, and preparation for an onsite Magnet® survey visit. Once the documents are reviewed and scored, the next step is an onsite survey to validate the documents and speak with nursing staff and their colleagues.

### ***Magnet® Ambassadors***

For the past year, Rachel Coumes, M.S.N., RN, NPD-BC, Magnet® Recognition Program Manager, has been working on assembling a Magnet® ambassador team made up of people from the Clinical Center Nursing Department, multiple Clinical Center Departments and colleagues from other ICs. The team works on Magnet® readiness, communication, and engagement within the Clinical Center. During September 2021 through October 2023, collaborative Magnet® rounding will occur. This involves the Magnet® program manager, nurse leaders, and the ambassadors rounding in clinical areas to interact with staff to discuss monthly Magnet® themes.

According to Dr. Jordan, the Ambassador team assembled three working subgroups: Certification Promotion and Support, Publicity and Media Campaigns, and Extradepartmental Outreach. In collaboration with the NIH Office of Strategic Planning and Management Operations, the nursing department developed another key component: a strategic plan, along with updated mission and vision statements and a comprehensive 3-year plan. The target date for completion is November 30, 2021.

### ***Communications Planning***

A key part of the Magnet® journey is communications planning. Ms. Coumes and the Magnet® team have been working with the Clinical Center's Office of Communications and Media Relations and with the Office of Patient Recruitment on a strategic plan for communications. Starting with the nursing department, the team will be working with Clinical Center departments and then with the broader NIH community. The plan is to increase the Magnet® presence in public settings, including the screens throughout the Clinical Center, the Clinical Center newsletter, and external-facing websites to broaden the message about the journey to Magnet® recognition. Ms. Coumes has begun communicating with the nursing department via email and video (the Magnet® Minute). The acting Chief Nurse Officer will also report during quarterly Clinical Center business meetings attended by department heads and chiefs. The Magnet® program director will provide Magnet® education and updates at Clinical Center Department staff meetings beginning November 2021.

### ***Discussion***

Dr. Forese acknowledged that the Magnet® journey is long but worthwhile. She congratulated Dr. Jordan on progress achieved. Ms. Williams-Brinkley expressed support of the effort, which will be key in solving staffing issues by improving the work environment. She encouraged Dr. Jordan maintain Magnet® status once achieved.

## **Hospice Care: Pain and Palliative Care Service and Spiritual Care Department**

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

Dr. Cohen-Berger explained that the hospice unit grew out of the missions of two programs—the Pain and Palliative Care service and the Spiritual Care Department—both of which focus on the physical, spiritual, psychological, and social needs of Clinical Center patients at the end of life. Research participants may be followed at the Clinical Center for days or years; if and when they are ready, they may transfer to the hospice. On any given day, the team sees about a quarter of all inpatients. Usually, half of patients on the service are younger than 39.

### ***Education and Research***

According to Dr. Cohen-Berger, the service offers a fellowship program in hospice and palliative care through a collaboration with Holy Cross Hospital. All oncology fellows from NIH and WRNMMC rotate through the service, as do pain fellows from WRNMMC and palliative care fellows from George Washington University.

Palliative care research has been focusing on spirituality and mindfulness practices and on developing and validating a psychosocial spiritual assessment tool. Other research projects have evaluated mindfulness-based self-care and the effects of nature adventure experiences with or without mindfulness practices for healthcare providers working with patients with COVID-19. A paper published in *JAMA* demonstrated that five sessions of mindfulness over the course of 5 weeks reduced stress and anxiety.

## ***Palliative and Hospice Care***

Dr. Cohen-Berger said that the Pain and Palliative Care service has three missions: clinical care, education, and research. At NIH, palliative care is integrated into care from the beginning of a patient's involvement with the Clinical Center. The service collaborates not only with the Spiritual Care Department but also with therapy, social work, nutrition, psychiatric, and bioethics. Integrative treatment modalities include acupuncture, mindfulness, pet therapy, and art therapy.

In 2005, the Palliative Care Service introduced a bereavement program that stays in touch with families with cards and telephone calls to be watchful for signs of complicated grief. The Spiritual Care Department also coordinates annual memorial services.

The goal of hospice care is comfort at the end of life. The Palliative Care team created a separate hospice order set to facilitate transfer of patients to the hospice unit. Dr. Cohen-Berger presented photos of two hospice rooms that opened in July 2018. Each room has an attached family room equipped with a chair, sofa bed, microwave, and refrigerator. Pets are allowed to visit patients in the unit.

Hospice nurses are from an oncology unit in the Clinical Center. Their training includes a rotation through Montgomery Hospice, observation hours with the NIH Pain and Palliative Care Team, and educational sessions.

On average, patients in the hospice are transferred from hospital units about an average of 30 days after the date of hospitalization. The average time in a hospice bed is 6.6 days, but some patients are engaged as long as 35 to 70 days. Unlike at other hospice units, where patients can remain for only about 5 days, people may remain in hospice care at the Clinical Center as long as they need. Some patients have transferred from the Clinical Center's hospice unit to a hospice center nearer their homes. About a third of patients who died in the Clinical Center were in the hospice unit, with the remainder in the ICU and the pediatric unit.

Since July 2018, 54 patients ages 29 to 92 years have been served by hospice care. NCI is the main user (83%). There are opportunities for rapid autopsy and organ donation for hospice patients.

## ***Spiritual Care***

Mr. Pollack offered the following definition of *spirituality*: “the aspect of humanity that refers to the way individuals seek and express meaning and purpose and the way they experience their connectedness to the moment, to self, to others, to nature, and to the significant or sacred.”<sup>1</sup> Religion fits into this definition as do other value systems through which humans find sources of meaning and purpose. Most people can recognize their values in this definition, according to Mr. Pollack. Spirituality is especially important to people at the end of life Whether or not they are religious.

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<sup>1</sup> Puchalski C, Ferrell B, Virani R, Otis-Green S, Baird P, Bull J, et al. Improving the quality of spiritual care as a dimension of palliative care: the report of the consensus conference. *J Palliat Med.* 2009;12:885-904.

Mr. Pollack pointed out that not everyone has a religion, but everyone has a spirit. He speaks with people from all over the world who have differing life views about grief and loss. The staff—professional chaplains and supervised trainees—are attuned to working across cultures. The Spiritual Care Department is dedicated to individualized care and meeting a person where they are. The goal is to serve people with a system of spiritual care, rooted in compassion, including all providers who come in contact with patients.

### ***Providing Spiritual Care***

All patients and their families are seen within 24 hours of admission to hospice. Most have a preexisting relationship with a chaplain from their inpatient stay or clinic appointments.

The team also provides spiritual care for Clinical Center hospice nurses and other hospice caregivers that includes one-on-one spiritual support, debriefing groups, and memorial services. People have opportunities to discuss challenges, and staff can encourage them and let them know they are doing a good job and making a difference for patients and families.

### ***Shared Goals for the Future***

Dr. Cohen-Berger spoke of plans to train more hospice nurses. There has been some turnover, and there is a need to expand training for pediatric hospice care. Trainees currently receive training through the End-of-Life Nursing Education Consortium. Collaboration with the ICU continues, with a focus on determining optimal setting for care at the end of life: hospice or the ICU.

Dr. Cohen-Berger concluded with a salute to the Clinical Center's patient-heroes. They can benefit from early, available, integrative, and reassuring palliative interventions as they approach the end of life.

### ***Discussion***

Dr. Forese thanked the presenters for a touching and impressive presentation. There are similarities between the Clinical Center's program and programs at larger centers, despite the small size of the Clinical Center's hospital.

Dr. Hait said he knew Dr. Cohen-Berger when she was a fellow, before palliative care existed. He said it was fantastic to see her accomplishments.

Dr. Gilman said he was proud of his role in establishing the hospice in the Clinical Center. The unit is unique in that these people are research participants, which is no small commitment. Everyone hopes to live a life of meaning, but it is rare that people have deaths that have meaning and help others.

## **Interactions of NIH and the Clinical Center with Pharmaceutical Companies**

*Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH*

Dr. Tabak recalled that this presentation was in response to a request from the Board's previous meeting.

Many NIH researchers collaborate with industry in a mutually beneficial manner. Collaborations support the development and testing of agents, procedures, and interventions at NIH and the

Clinical Center, especially through clinical trials. Dr. Tabak explained that interactions with industry are supported by a variety of mechanisms, outlined in the following sections.

### ***Cooperative Research and Development Agreement (CRADA)***

Dr. Tabak said that a CRADA is any formal written agreement between one or more federal laboratories and one or more nonfederal parties for conducting specified research or development. Under a CRADA, the government, through its laboratories, can provide personnel, services, facilities, equipment, or other resources with or without reimbursements, and the collaborator can provide funds, personnel, services, facilities, equipment, or other material and/or technical resources for the collaboration. A CRADA is not a federal contract, grant, or cooperative agreement. About 450 CRADAs are currently active at NIH. The collaborator can supply funds to support the research plan but not salaries or benefits for federal employees. CRADAs offer the collaborator licensing opportunities for inventions that arise during the research. The effort must be collaborative, not fee for service, so a CRADA cannot substitute for an NIH purchase contract. Examples of accomplishments made possible through CRADAs include projects between industry and the National Heart, Lung, and Blood Institute (NHLBI) to develop therapies for COVID-19; with the National Cancer Institute (NCI) in a Phase II trial to evaluate a combination of nivolumab, vancomycin, and tadalafil for liver cancer; and with the National Institute of Allergy and Infectious Diseases (NIAID) to conduct a Phase II/III trial of pozelimab in CD55 deficiency.

### ***Clinical Trial Agreement (CTA)***

Dr. Tabak informed that a CTA is a partnership between NIH and an outside entity to conduct clinical trials to test experimental drugs, devices, procedures, and interventions on human research participants. CTAs are one of the most common mechanisms to obtain investigational drugs for clinical research at NIH. CTAs are easier to implement than CRADAs and may be appropriate if the collaborator's contribution is small and the licensing option may not be equitable. The collaborator may provide funds that would be accepted under the agency's gift acceptance authority.

Examples of CTAs include an NCI-sponsored Phase I trial of the orphan drug zotiraciclib for treating glioma, four CTAs to support NIAID COVID-19 vaccine development, also a CTA to support an NIAID–Gilead collaboration for testing remdesivir as a COVID-19 treatment.

### ***Research Collaboration Agreement (RCA)***

RCAs are agreements between NIH and outside entities to conduct collaborative research other than clinical trials.

### ***Material Transfer Agreement (MTA)***

Dr. Tabak said that with an MTA, the outside entity provides research materials only. There is no research collaboration. Neither a licensing option nor rights for commercial purposes may be granted. MTAs are often used for basic science research (e.g., mouse lines). Examples include NIAID's MTAs with 75 entities to share SARS-CoV-2 stabilized spike proteins for vaccine development. NIAID also used MTAs to develop a monoclonal antibody treatment for Ebolavirus disease.

### ***Conditional Gifts***

This mechanism entails gifts given to the government for a specific purpose.

### ***Direct Purchases for Standard-of-Care Drugs***

Dr. Gilman said that the Clinical Center procures 95% of standard-of-care medications from a national prime-source vendor. Medications provided by outside entities under investigational new drug applications are kept separate in an investigational drug control unit rather than the general pharmacy and used only for specific protocols. Investigational drugs may be prepared in the same clean room as the Intravenous Admixture Unit, however. The Clinical Center often uses a third-party fiscal intermediary for obtaining investigational drugs.

### ***Considerations for Human Subject Research Collaborations***

Dr. Tabak said that the principles of the NIH Genomic Data Sharing (GDS) policy (<https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/>) apply to clinical trials conducted under industry collaborations. GDS applies even if NIH funds do not support the genome sequencing and the industry partner performs the testing. In addition, certificates of confidentiality apply to any exchange of material or data.

Dr. Tabak listed some recent NIH and industry collaborations leading to FDA action.

Status	Drug Name	Drug Type	Target	Investigator/s	Approval Date	Collaborator
Approved for marketing	Avelumab	Anti PD-L1 antibody	Merkel cell carcinoma	Gulley/Schlom	March 2017	EMD Serono Inc./Pfizer
Approved for marketing	Yescarta	CD19 CAR T	B-cell lymphoma	Kochenderfer/Rosenberg	October 2017	Kite Pharma
Approved for marketing	Lumoxiti	Anti CD22-toxin	Hairy cell leukemia	Pastan/Kreitman	September 2018	MedImmune/AstraZeneca
Approved for marketing	Selumetinib	MEK inhibitor	NF1	Widemann/Gross	April 2020	AstraZeneca
Approved for marketing	POMALYST	Immunomodulator	Kaposi sarcoma	Yarchoan	May 2020	Celgene
Approved for marketing	Nivolumab and cabozantinib	Checkpoint inhibitor plus tyrosine kinase inhibitor	Advanced renal cell carcinoma	Apolo	January 2021	Bristol Myers Squibb

Status	Drug Name	Drug Type	Target	Investigator/s	Approval Date	Collaborator
Approved for marketing	Idecabtagene vicleucel	CAR T-based gene therapy	Multiple myeloma	Kochenderfer	March 2021	Bristol Myers Squibb
Approved for marketing	Belumosudil	Kinase inhibitor	Chronic graft-versus-host disease	Pavletic	July 2021	Kadmon Holdings
Approved for marketing	Belzutifan	Hypoxia-inducible factor inhibitor	Cancers associated with von Hippel-Lindau disease	Srinivasan	August 2021	Merck
Break-through therapy	LN-145	TIL therapy	Advanced cervical cancer	Surgery Branch	May 2019	lovance Biotherapeutics
Break-through therapy	MK-6482	Hypoxia-inducible factor-2 alpha inhibitor	von Hippel-Lindau disease-associated renal cell carcinoma	Linehan/Srinivasan	July 2020	Merck
Orphan drug	Zotiraciclib	Kinase inhibitor	Glioma	Wu	December 2019	Adastr
Orphan drug	PRGN-2012	Immunotherapy	Recurrent respiratory papillomatosis	Gulley/Schlom	March 2021	Precigen

More information is available at <https://www.ott.nih.gov>.

### ***Discussion***

Dr. Gilman said that an issue has arisen a few times when an outside entity has asked the Clinical Center to report adverse events only to the pharmaceutical company and not to the FDA. The Clinical Center will not accept such terms; being an operational division of the U.S. Department of Health and Human Services, it would be problematic for NIH to not report an adverse event to the FDA. That said, the Clinical Center is generally willing to report adverse events simultaneously to the company and the FDA.

Dr. Gilman said that another issue that crops up occasionally is when a company says that it is donating an investigational drug but the situation is really a CRADA type. In these cases, the company is just seeking resources to handle the extra work involved in a CRADA.

Michael Gottesman, M.D., said that the great majority of agreements are handled through the IC technology transfer service units of the investigator, not the Clinical Center. (Dr. Gilman clarified that interventional radiology is an exception.)

Dr. Hait said he was impressed by the rapid progress made through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership in developing treatments and vaccines for COVID-19. Are there lessons learned that could be applied more broadly? Dr. Tabak was confident that there are generalizable lessons. For example, one of the most important things was having people from academia, industry, and government together in the same virtual room. Those discussions helped things move rapidly. Prioritization schemes were well served through collective wisdom rather than having any one sector trying to go it alone. NIH would like to replicate this invaluable partnership approach in operations.

Dr. Shannon noted that the Bayh-Dole Act allows commercialization of findings from federal grants; that change revolutionized discovery at academic and nonprofit institutions. How do for-profit companies return value to shareholders? Dr. Tabak clarified that CRADAs do allow future considerations through licensing. Dr. Gottesman said that NIH’s technology transfer staff negotiate the terms of agreements. If a CRADA is initiated, NIH tries to avoid exclusive licensing terms in order to get other companies operating in the space. There are strong barriers between researchers and companies to prevent conflict of interests. Intermediaries handle transactions. If there is exclusive licensing, there are usually terms that give royalties to laboratories of the relevant NIH IC. The maximum that an investigator can receive is capped at \$150,000, which is a generous sum but not excessive compared with NIH salaries.

### ***Action Item***

- The Board recommended that NIH develop generalizable lessons learned from ACTIV to expand use of this successful public–private partnership model.

### **Adjournment**

Dr. Forese thanked the presenters, NIH Clinical Center staff, and Board members.

A member recommended a children’s book, [\*How a Boy from Brooklyn Became America’s Doctor\*](#). Dr. Gilman pointed out that Disney+ is streaming a *National Geographic* documentary called *Fauci*.

The next Board meeting is scheduled for April 1, 2022.

Dr. Forese adjourned the meeting at 12:54 pm.

/Laura Forese/

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

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, New York–Presbyterian Hospital

/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

AAV	adeno-associated virus
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ADC	average daily census
ANCC	American Nurses Credentialing Center
CARES	Coronavirus Aid, Relief, and Economic Security (Act)
CAUTI	catheter-associated urinary tract infection
CCRHB	Clinical Center Research Hospital Board
CEO	Chief Executive Officer
CLABSI	central-line–associated bloodstream infection
COVID-19	coronavirus disease 2019
CRADA	Cooperative Research and Development Agreement
CRISPR	clustered regularly interspaced short palindromic repeats
CTA	Clinical Trial Agreement
DART	days away, restricted, or transferred
FDA	U.S. Food and Drug Administration
FSA	focused standards assessment
FY	fiscal year
GDS	Genomic Data Sharing (Policy)
HHS	Department of Health and Human Services

ICs	Institutes and Centers
ICU	intensive care unit
MTA	Material Transfer Agreement
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
RADx	Rapid Acceleration of Diagnostics
RCA	Research Collaboration Agreement
SAFER	Survey Analysis for Evaluating Risk
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
TRC	total recordable cases
WRNMMC	Walter Reed National Military Medical Center