U.S. Department of Health and Human Services

National Institutes of Health

Fifth Meeting of the
Clinical Center Research Hospital Board

July 14, 2017

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Executive Summary

The fifth meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on July 14, 2017, on the main campus of NIH. The meeting was open to the public and was webcast live.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:02 a.m. and welcomed all those in attendance. She reviewed the highlights from the last meeting and introduced the agenda for this meeting.

Francis S. Collins, M.D., Ph.D., NIH Director, acknowledged the time and effort put in by the CCRHB members. He presented a series of photographs depicting high-profile meetings that have occurred in recent months. A Discovery documentary, *First in Human*, about the NIH Clinical Center is set to air on August 10, 2017. NIH is planning to launch a publicity campaign about the film and is gearing up for a spike in inquiries about NIH research.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, unveiled the new mission statement and guiding principles for the Clinical Center. He highlighted progress in filling key positions and with centralization of functions related to safety and clinical quality. Other notable successes include the Morbidity & Mortality (M&M) Conferences that use a new format that avoids "naming, shaming, and blaming" and have been drawing large crowds, enhancement of facilities and staff to improve pediatric care in the Clinical Center, dedication of space as hospice care rooms, progress with the Center for Cellular Engineering, and implementation of a new tool (I-PASS) to facilitate better communications and transitions when patients are moved among units in the Clinical Center.

John Gallin, M.D., Associate Director for Clinical Research and Chief Scientific Officer, Clinical Center, focused on the new scientific review policy, which describes the minimum requirements for the NIH Institutes' scientific reviews of clinical protocols in the Intramural Research Program. The policy includes a mechanism for assigning priorities for protocols across Institutes and Centers (ICs) that use scarce resources. The priority-setting exercise was piloted by using the Clinical Center's cell-processing facilities as a test case.

Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality, reviewed the principles of high reliability and underscored the importance of implementing strategies to reduce the likelihood of harm. She introduced the new event-reporting tool, the Safety Tracking and Reporting System (STARS). All key implementation milestones were achieved. The number of reports per month has jumped from 350 to more than 500 since the new system was put in place.

The morning ended with a closed session.

Michael Gottesman, M.D., Deputy Director for Intramural Research, briefed the CCRHB on the outcomes of the recent reaccreditation site visit conducted by the Association for the Accreditation of Human Research Protection Programs. NIH was fully accredited for an initial 3 years, beginning in 2014. The reaccreditation site visit occurred during December 12–16, 2016. Over a period of 5 days, four site visitors conducted 114 interviews of institutional review board (IRB) chairs, IRB members, IRB support staff, and IC and Human Research Protection Program (HRPP) leaders. As a result of recommendations received, NIH leadership is reorganizing the IRBs overseeing intramural research and standardizing scientific and IRB reviews of protocols.

The tension between clinical care and clinical research was the topic of a presentation by Christine Grady, Ph.D., M.S.N., RN, Chief, Department of Bioethics. She explained the role of bioethicists in the Clinical Center and offered several examples to demonstrate how bioethics consultations can help clarify complex issues regarding research participation and informed consent.

Stewart Simonson, J.D., served as the facilitator for the Clinical Center Engagement Project, which concluded earlier this year. Mr. Simonson presented a report on the outcomes of the Clinical Center focus groups. He synthesized the feedback under five themes and developed a set of 50 recommendations based on the focus groups' concerns and suggestions to enhance research, safety, and quality of care in the Clinical Center.

Dr. Forese and Dr. Collins thanked the board members for their insights. Dr. Forese adjourned the meeting at 3:06 p.m.

The next face-to-face CCRHB meeting is scheduled for October 20, 2017.

Meeting Summary

Friday, July 14, 2017

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 fifth meeting of the CCRHB took place on July 14, 2017, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and was webcast live. Dr. Forese called the meeting to order at 9:02 a.m. and welcomed all present. She announced that Ruth Brinkley, M.S.N./Adm., and Brig Gen James Burks, M.B.A., M.M.A.O.S., were unable to attend. Jeanette Erickson, D.N.P., RN, participated via teleconference.

Dr. Forese noted that the CCRHB has been in existence for 2 years. She reviewed the topics covered during the last meeting and then introduced the agenda for this meeting.

NIH Director's Remarks

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

Dr. Collins thanked the CCRHB members for the time and energy they have invested in their important roles. Everything is moving in a positive direction thanks to the efforts of chief executive officer (CEO) James Gilman, M.D., and other NIH leaders and staff. The NIH Clinical Center continues to be an amazing place, a source of hope for many patients who have rare and seemingly intractable diseases.

Dr. Collins announced that Dr. Forese had been selected as one of the 50 most powerful women of 2017 by *Crain's New York Business* magazine.

Dr. Collins presented a series of photographs depicting high-profile meetings that have occurred in recent months. In February, Chairman Tom Cole of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies and several subcommittee members came to NIH and met with a group of trainees (post-baccalaureates and post-doctoral fellows). The Subcommittee is responsible for marking up the fiscal year (FY) 2018 budget, which includes an increase for NIH. The meeting also is an important opportunity for Congressional members to hear from the next generation of scientists. Health and Human Services (HHS) Secretary Tom Price toured NIH facilities in February. Senator Shelley Moore Capito came to NIH to discuss Alzheimer's disease and the opioid crisis. Other visitors included Senate Committee on Appropriations Chairman Roy Blunt along with nine committee members—the largest delegation of senators to visit NIH. Former Speaker of the House Newt Gingrich visited NIH to learn more about regenerative medicine and stem cell research. Senator Christopher Coons also came to NIH, as did HHS Assistant Secretary for Administration John Bardis, whose position is particularly important because it controls HHS hiring. The senator met some patients and toured the co-generation plant, which he described as the most sophisticated energy system he has seen outside of a nuclear facility. Senator Jerry Moran spent an afternoon learning about neuroscience and Alzheimer's disease at NIH.

In April, Siddhartha Mukherjee, M.D., author of *The Emperor of All Maladies* and a new book, *The Gene*, took part in an author meet-and-greet event as part of a new program called the NIH

Big Read. Astronaut Kate Rubins, Ph.D., also visited NIH recently. She was the first person to sequence DNA in space. Bill Gates was at NIH for an annual meeting of NIH staff and senior Bill & Melinda Gates Foundation staff. Opera star Renée Fleming was a driving force behind a program on music and the brain, arranged via a partnership with the Kennedy Center.

Dr. Collins and William Li, M.D., of the Angiogenesis Foundation, escorted several children being treated at the Clinical Center and their families to a U2 concert. The Edge (U2's guitarist) met with the families backstage.

Jim Parsons, star of *The Big Bang Theory*, is the narrator for a Discovery documentary, *First in Human*, about the NIH Clinical Center. It is set to air on August 10, 2017. The film was screened at the Reagan Building in Washington, D.C. Senators Blunt and Cole attended and spoke about the excellent research and patient care at the Clinical Center. After a screening for television critics, NIH will launch a publicity campaign about the film and gear up for a spike in inquiries about NIH research.

NIH Clinical Center CEO: Update

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

Dr. Gilman revealed the new Clinical Center's new mission statement, "We provide hope through pioneering clinical research to improve human health," and a set of guiding principles. Dr. Gilman updated the Board on steps being taken in accordance with these principles.

The first guiding principle focuses on safe patient care: "individual and collective passion for high reliability in the safe delivery of patient-centric care in a clinical research environment." To this end, Dr. Gilman highlighted progress made in filling key positions. The search process for the chief nursing office/chief nursing executive (CNO/CNE) is well under way. Dr. Gilman will be issuing a charge to the search committee for a chief operating officer on July 17. HHS has approved that new position. Colleen McGowan, M.H.A., FACHE, is no longer the Acting Executive Officer; she is officially the Executive Officer now. In addition, a nationwide search for a radiology and imaging science chief has been launched.

Dr. Gilman presented an updated organizational chart showing how research support in the Clinical Center is being centralized. Most positions that focus on regulatory compliance have been transferred to the Clinical Center, along with the funds budgeted for those activities. These positions are now at the operational level. Oversight will remain at the level of the Deputy Director for Intramural Research (DDIR).

The Medical Executive Committee (MEC) approved the concept underpinning the formation of the Patient Safety, Clinical Practice, and Quality Committee (PSCPQC).

In terms of patient safety, some important events have occurred since the last meeting of the CCRHB. A second Morbidity & Mortality (M&M) Conference using the new format (which avoids "naming, shaming, and blaming") resulted in an overflow crowd in the Lipsett Amphitheater. The theme was "What Have You Forgotten Lately?" The larger Masur Auditorium will host the next M&M conference, which will focus on transitions of care and communication.

Regarding transitions of care, Dr. Gilman pointed out that transferring patients between services or units is fraught due to episodes of poor communication and the lack of a mechanism for

coordinating multiple steps carefully. To smooth these transitions, nurses in all areas have been brought under the supervision of the Clinical Center Nursing Department. In addition, an evidence-based handoff program called "I-PASS" will be implemented. The Clinical Center purchased a license for the full campaign, which will be rolled out soon.

Dr. Gilman described changes in the works to improve care of pediatric patients. Planning for the new pediatrics observation unit is underway. The Clinical Center is hiring its first pediatrics hospitalist. Also, pediatrics expertise is being added to the Code Blue Team.

The Institutes and Centers (ICs) are making changes to improve patient safety in the Clinical Center. The National Cancer Institute (NCI) moved to a hospitalist model to cover inpatients during at least a portion of the day. The National Institute on Deafness and Other Communication Disorders (NIDCD) established a contract for consultation and surgical expertise for specialized procedures that Clinical Center surgeons do infrequently.

Focusing on guiding principle 2, which is about diversity and inclusion of people and ideas, Dr. Gilman spoke about the graduation ceremony for Project Search. This Clinical Center program focuses on job skill training for young people with intellectual and developmental disabilities. Participants spend a month in training at the Clinical Center and sometimes in various ICs. Other federal institutions, including the Smithsonian Institution, have adopted this training model. Partners include SEEC (Seeking Equality, Empowerment, and Community for People with Developmental Disabilities) and Ivymount School.

Guiding principle 3 calls for "compassion for our patients, families, and one another." Ann Berger, M.D., Chief of Pain and Palliative Care Services, identified resources to set up dedicated space for two hospice suites for patients and their families. Construction of more permanent facilities will begin in the spring,

Guiding principle 4 focuses on innovation in preventing and solving problems. Dr. Gilman explained that all protocols are reviewed for resource implications. In addition, complex, high-risk protocols undergo failure mode and effects analysis (FMEA), a measure that the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) cited in a positive way. In addition, strategic plan development kicked off in June with a 4-hour Clinical Center leadership meeting. A follow-up meeting of Clinical Center leaders will take place, followed by meetings involving wider representation from the ICs.

Dr. Gilman provided some statistics on the average daily census in the Clinical Center: An uptick in the census—the first in some time—occurred in May and June of this year; much of the increase was attributed to pediatric admissions. Most likely, the Center for Cellular Engineering (CCE) will contribute to future increases in the census.

Guiding principle 5 calls for accountability in the use of resources. Dr. Gilman said that the midyear sweep provided an opportunity to make investments for patient safety. The first quarterly business planning meeting was held in June. Dr. Gilman will present information on 2017 utilization metrics and budget execution, as well as on the outlook for the 2018 budget, to the Clinical Center Governing Board (CCGB) on July 20. Work has begun on a formal business plan for the CCE, with the help of an additional administrative person who joined the Clinical Center's Department of Transfusion Medicine.

In keeping with guiding principles 6 and 7 ("excellence in clinical scientific discovery and application" and "commitment to professional growth and development," respectively), Dr.

Gilman acknowledged the need for succession planning and for professional recognition of Clinical Center staff members. During upcoming town hall meetings, NIH leaders will be recognizing people for government service, as well as administrative and scientific excellence.

Discussion

Richard Shannon, M.D., noted that a lot of work is going on in the Clinical Center. He remarked that inpatient census statistics in hospitals of this size are declining nationwide. That trend is due in part to increased outpatient services. Dr. Gilman said that the Clinical Center's outpatient census for 2017 has been down. The CCE likely will improve the average daily census, as will increases in operating room staff and pediatrics support.

Reed Tuckson, M.D., referred to the organizational structure and asked how these positions fit together while still providing the capacity to implement centralization of common functions as opposed to specialized functions. Dr. Gilman said that a single office (the PSCPQC) is dedicated to patient safety and quality for both the Clinical Center and the ICs. Each IC has a clinical director. If there is a problem with an IC physician or an IC-contracted physician, Dr. Gilman would bring it to the attention of the IC's clinical director.

In response to another CCRHB member's question, Dr. Gilman clarified that NCI hospitalists cover only NCI patients. Some ICs do not like the hospitalist model; their investigators prefer to provide care for their patient-participants. Some of NIH's best and well-known researchers are also the best clinicians.

Dr. Tuckson asked whether nurses are under one department, and Dr. Gilman explained that some research nurses are employees of the ICs, but nurses providing care are Clinical Center staff and serve all patients. In response to a question about physician coverage, Dr. Gilman said that some ICs prefer to have their dedicated research teams cover all elements of clinical care. The responsibility for the quality of care lies in the Clinical Center. At night, an on-call clinical fellow would come in. There is a mechanism to deal with problems with the quality of care. Care is delivered via different structures but with high quality. Quality of care is constantly assessed.

Dr. Tuckson expressed interest in seeing data from the quality dashboard reports categorized by IC. The CCRHB would like to see whether there are any deviations between ICs that might signal problems with the decentralized process. Dr. Gilman said that some ICs have very few inpatients at the Clinical Center and that NCI has a very diverse patient population.

Peter Pronovost, M.D., Ph.D., observed that the flexible approach seems to be working but that standards should be consistent regardless of whether care is provided by IC or Clinical Center staff. Laura Lee, RN, thought it would be possible to develop a central policy with standards or measures to clarify what is expected. Dr. Forese said that the CCRHB is interested in tracking those measures to see whether there are any concerns. In a model where there are different ways of providing coverage, certain standards need to be measured and tracked.

Beatrice Bowie offered a personal example from her experience as a research participant in a National Heart, Lung, and Blood Institute (NHLBI) study. When she became acutely ill, she would call the page operator, who then called the physician on call. By the time she arrived at the Clinical Center, the staff would be ready. Care was coordinated through the clinical fellow on call in consultation with the investigator who was familiar with Ms. Bowie's medical history.

Dr. Collins asked about preparations for dealing with the deluge of inquiries expected when the Discovery special airs. Dr. Gilman said that the patient recruitment office is working with the

Clinical Center's director of communications to expand telephone trunk lines and boost staffing to answer calls.

Follow-Up Items:

- Next week, Dr. Gilman will get the final plan for the communications ramp-up (for the Discovery special), and he will pass it on to the CCRHB.
- The CCRHB would like to see a central policy developed with standards or measures to ensure consistent and excellent quality of care in the Clinical Center provided by the various ICs.
- The CCRHB would like to see quality dashboard reports categorized by IC in order to detect deviations between ICs that might signal problems with the decentralized process.

Policy for Scientific Review of Clinical Protocols Using the Clinical Center

John Gallin, M.D., Associate Director for Clinical Research and Chief Scientific Officer, Clinical Center

Dr. Gallin discussed the scientific review procedure for clinical protocols, and he outlined the process for prioritizing protocols that rely on the scarce resources of the Clinical Center. The prioritization process was based on input received during a series of meetings involving multiple people. The Intramural Research Program (IRP) had more than 2,000 active protocols in 2016: 1,636 in the Clinical Center and 535 off site. Of the 1,636 clinical trials in the Clinical Center, about 800 were interventional, and most were phase 1 or 2. The remainder were natural history studies, training protocols, and screening protocols.

The new scientific review policy describes the minimum requirements for the ICs' scientific reviews of IRP clinical protocols. The policy includes a mechanism for assigning priorities for protocols across ICs that use scarce resources. Following the initial scientific review, the protocol should be ready to hand off to the IRB for safety review.

A standard tool will be used for protocol authoring, with defined templates for writing protocols. Initially, the templates will be Word-type documents, but the goal is to link the templates to a relational database. Such a system would help IRBs identify issues that cut across certain types of protocols.

According to Dr. Gallin, scientific reviews comprise three broad elements:

- Concept review by laboratory, branch, or scientific director level, based on the IC's discretion.
- Initial review of the complete protocol by the scientific review committee, with oversight by the clinical and/or scientific director and, in some cases, extramural reviewers.
- Ongoing reviews annually at the time of IRB review and every 4 years thereafter. The quadrennial in-depth review will involve extramural reviewers to decide whether the study should continue and whether the study is using the best methods.

Due to scarce resources at the Clinical Center, not all protocols receiving outstanding scientific reviews can be implemented promptly. The process to date has largely been on a "first come, first served" basis. Already, some protocols are not being done or are being conducted slowly.

Therefore, the scientific review policy includes a process for prioritizing protocols that use scarce resources, such as the following:

- Cell processing
- Apheresis services
- Imaging (magnetic resonance imaging [MRI] and MRI positron emission tomography/computed tomography [PET/CT])
- Hematopoietic stem cell transplantation or bone marrow transplantation
- Drug compounding
- Operating rooms
- Metabolic chambers
- Drug pharmacokinetic/pharmacodynamic testing
- Microbiological testing of sterile products
- Special testing in laboratory medicine
- Pediatrics—deep sedation for procedures
- Biomechanics laboratory

Cell processing served as a pilot case to come up with a prioritization method. NCI is the most frequent user of this service, followed by NHLBI and the National Institute of Allergy and Infectious Diseases (NIAID). There has been considerable growth in the demand for this scarce resource. Thirty-seven protocols are being implemented currently; of these, 13 were queued for later implementation. Eight new protocols are currently in development. Twenty additional protocols are projected for implementation through 2020.

Staff and space are limiting resources. With Dr. Collins's support, additional space is being dedicated to cell processing. In 3T (the current space), four rooms are available for complex investigational products, and one room is for standard-of-care transplants involving minimal cell manipulation. Trailers were brought in for NCI personnel to use in vaccine manufacture. By 2019, cell processing should no longer be a scarce resource in terms of space. The Department of Transfusion Medicine currently employs 30 staff to manage 37 protocols. An estimated 12 additional staff would be needed to handle the 13 protocols currently in the queue. For the NCI Surgery Branch, 12 staff currently manage 8 protocols, and 7 additional staff are needed.

NIH needs to start prioritizing protocols now to ensure that the most compelling studies are performed. The prioritization system has to be fair and transparent, and it must include a mechanism to resolve disputes. The evaluation process should include a variety of stakeholders to ensure that clinical protocols address important clinical questions and to ensure optimal use of the Clinical Center's resources. Outcome measures are necessary to evaluate the process.

The IC Directors' Subcommittee on Protocol Prioritization, chaired by Dr. Gallin, will oversee the priority-setting process.

Both new and active protocols would be batched and prioritized. Dr. Gallin noted that ethical considerations apply to active protocols; no patient participating in a protocol or scheduled to participate will be denied enrollment. Early career investigators and new IC users of scarce resources receive special consideration. The clinical directors undertake an initial prioritization within their ICs. These priorities would be harmonized across ICs with the other clinical directors, using a new prioritization tool.

The responsible Clinical Center department would work with the clinical directors to clarify how many of the top-priority protocols could be handled with current capacities. The ICs could identify alternative off-site locations for protocols not accommodated by the priority-setting system. A subcommittee of IC Directors will adjudicate issues and make recommendations to increase or decrease investments in a scarce resource.

Dr. Gallin then presented the list of prioritized protocols relying on cell-processing facilities. Thirteen protocols were previously deferred but have risen through the ranks via this prioritization process. Dr. Gallin will notify investigators about the results. When new cell-processing resources open, the Clinical Center will be able to accommodate more protocols.

Next steps include implementation of the new policy, identification of another scarce resource for prioritization, and evaluation of metrics to monitor the success of the new policy. Dr. Gallin noted that some protocols use multiple scarce resources, adding complexity to the process.

In conclusion, Dr. Gallin said that having a policy on scientific review, along with prioritization of scarce Clinical Center resources, will ensure continued scientific excellence while providing a rational and transparent process for moving forward.

Discussion
Mr. O'Neill asked how space was determined to be a limiting factor. Did the analysis take into account 24-hour availability of resources? In industry, sometimes operations are at 100 percent of capacity, but often some additional capacity can be found if scrap rates are decreased. Dr. Gallin said that the cell-processing facilities have to meet standards of Good Manufacturing Practices (GMP). The requirements of the Food and Drug Administration (FDA) are very strict. For example, while one product is being made, the space cannot be used for another product. Outside consultants are being brought in to advise NIH on ways to speed up processes or do more with the space available. Dr. Forese stated her support for consulting experts to get some ideas for scarce resources, such as imaging.

Dr. Pronovost congratulated Dr. Gallin and the subcommittee on the excellent progress made with the challenging and potentially contentious process. The ratio of the number of protocols to the number of hospital beds is impressive. The Clinical Center is a very research-intensive place. The numbers do not really convey how much research is being accomplished, given the small number of beds.

Regarding scientific reviews, Dr. Pronovost asked whether safety and risk are assessed (e.g., availability of resuscitation equipment for antigen-challenge studies). Dr. Gilman said that for high-risk protocols, NIH conducts FMEA at the front end instead of root cause analysis at the back end. Dr. Pronovost pointed out that reducing risks makes for better science and safer care by reducing protocol violations.

Dr. Collins found it helpful to see the mapping of future resources. Is there a way to track 1 or 2 years in advance to try to anticipate what could be a burgeoning demand for cell-processing services? Dr. Gallin shares this concern because of the great progress in the field. The priority-setting process will have to be undertaken regularly to ensure that Clinical Center priorities align with scientific priorities.

Dr. Tuckson asked whether the protocol-authoring tool would lead to more standardized data capture. Dr. Gallin said that investigators should have an idea of what the data will look like as they are writing protocols. That approach would help populate clinicaltrials.gov and the

Biomedical Translational Research Information System, making reporting easier for NIH investigators. Dr. Gallin hoped that the authoring tool will help investigators deposit data in the central repository and make the data compatible with the data from all the collaborating ICs.

Dr. Shannon asked about the possibility of collaborating with other federal facilities or other nearby GMP facilities. Dr. Gilman said that Fort Detrick has "clean rooms," but they are not set up for cell-based therapies.

Dr. Shannon mentioned the staffing constraint, observing that the build-out is coming at a time when overall volumes are low. Would it be possible to cross-train staff and use flexible scheduling to meet surges in demand? Dr. Gallin said that most of the protocols require great specialization and training, making it difficult to move people around to meet varying demand.

Dr. Forese said that every organization is contemplating the use of people and how things might change with artificial intelligence and machine learning. That might not apply at NIH at this time, but perhaps we could start thinking about it for the future. Dr. Gallin remarked on a new closed system for cell manufacturing. Also, in terms of flexibility, the additional space has wheels and can be moved as needed.

Ellen Berty asked about ICs' feedback about the new process. Dr. Gallin reported that IC staff who have participated in the process have been very supportive. However, the community of scientists has been contentious. Dr. Gilman said that the process was not smooth; only thanks to the leadership of Drs. Collins and Gallin has progress been achieved.

Jeanette Erickson, D.N.P., RN, recommended cross-training and integrating clinical nurses into the work Dr. Gallin described. The new chief nurse might have to help support future changes.

Safety Tracking and Reporting System (STARS)

Laura Lee, RN, Chief, Patient Safety and Clinical Quality, Clinical Center

Ms. Lee reviewed the principles of high reliability and underscored the importance of implementing strategies to reduce the likelihood of harm. She introduced the new STARS tool for event reporting. Reporting of near misses and process issues has to occur at all levels of the organization, but most reports are generated by frontline staff at the patient care level.

If the environment does not support reporting, then no system will work. The organization needs to have a just culture that supports transparency and reporting. Ms. Lee gave a historical perspective on the former Occurrence Reporting System (ORS), which had a very inflexible architecture and limited data analytics capacity. It was difficult to share information organizationally. A punitive culture coalesced around the system so that "ORS" became a verb: "I will ORS you for that!" The Clinical Center leadership wanted to move away from that culture and system.

The new STARS has four basic objectives:

- User-centered, intuitive design
- A robust internal system for follow-up and communication
- A feedback loop for the submitter
- Dynamic data analytics and reporting functionality on the back end to understand what is going on and push the information out

The objectives were met on time and under budget. Ms. Lee reviewed the implementation strategies, starting with early focus groups of users and nonusers. She recalled that a "burning platform" in late 2015 triggered the change, allowing some critical patient safety programs to come to the fore.

The patient safety team undertook the following activities:

- Benchmarked academic medical centers

- Conducted extensive market research

- Initiated education on the culture of raising safety awareness and the concept of a just culture

- Hired a nurse informaticist and a nurse consultant with reporting experience

- Convened an interdisciplinary advisory group of Clinical Center and IC representatives who are respected organizational change agents to serve as a sounding board for the patient safety team

The patient safety team spent a great deal of time with the advisory group and stakeholders to reengineer workflow, define the role of the file manager, and conduct system testing. The tool was purchased from RL Solutions. The patient safety team leveraged the power of the vendor's user community. Training was creative, innovative, and intensive. A series of videos was produced about the new system and the principles of high reliability and just culture.

All key implementation milestones were achieved. The number of reports per month jumped from 350 to more than 500. The reports have been used in daily patient safety huddles and at the unit, IC, or department level. Physician-submitted reports are trending upward.

Ms. Lee highlighted the strong analytics capability of STARS, with several examples from the organizational dashboard depicting patient safety event data. Each event is ranked in terms of harm and organized by event type (e.g., unplanned admission, communication gaps). It is possible to also track contributing factors; Ms. Lee noted that human factors were the primary contributing factor. The most frequently reported contributing factor was a missed process step, meaning that someone skirted a procedure. STARS gives users the ability to understand the event and then design appropriate interventions.

Ms. Lee listed some of the patient safety opportunities identified:

- Moog pump over- or under-infusion
- Lapses in communication and transitions of care
- Pharmacy delays
- Pneumatic tube system failures
- Unprofessional conduct
- Service excellence

Using STARS does present some challenges, however, such as the following:

- *Organizational learning and feedback:* Peer review protections limit feedback to users. Submitters cannot have free access to all information.
- *Volume of reports:* Increased numbers of reports can affect the workflow and workload of file managers and patient safety and quality staff.

- *Organizational quality improvement capacity:* NIH lacks a formal quality/performance improvement infrastructure (e.g., Lean, Six Sigma).
- *Lingering pockets of punitive culture:* "I STARred you for that!"

Ms. Lee is looking forward to continuing an exploration of the data analytics capabilities of STARS. She and the rest of the patient safety team will work on engaging IC partners in use of the system for reporting and data analysis. The plan is to integrate clinical research-related events and improve physician usage. In addition, training is planned for managing safety events (systems failure vs. personal culpability).

Discussion

Mr. O'Neill spoke about using tools to detect improvements in worker safety (e.g., fewer falls, fewer needle sticks). Ms. Lee said that STARS is being used to detect clusters of similar events, act on the reports, and get uptake by staff. She cited an example of safety issues arising from use of wheeled chairs on linoleum floors.

Ms. Lee explained that problems with the Moog pumps were due to user error in understanding pump programming. Errors have fallen nearly to zero since training has been instituted.

Mr. O'Neill said he tends to react negatively to the category of human behavior. When organizations say that something is human behavior, one tends to think that it is something that cannot be fixed, because of human nature. Ms. Lee said that the safety team focuses on human interactions with technology. Dr. Shannon said that when human factors are identified as a source of problems, people often assume that they are the problem, but systems issues can lead to human factors. Management factors should be verbalized. Dr. Pronovost has written on this topic. Personal responsibility is important. On rounds, people could step up and acknowledge ownership of a problem. Dr. Shannon also said that putting in place systems for measuring performance is very important.

Dr. Shannon suggested engaging physicians around clinical work—for example, aiming to achieve near-perfect outcomes from bone marrow transplants. Select clinical outcomes that matter to the physicians and build engagement around that. It is critical to get the physicians involved. Ms. Lee said that physician-investigators have engaged on FMEA, reducing mortality rates in the intensive care unit and striving to eliminate sepsis cases.

Ms. Berty recommended positive reinforcement for people who have corrected or changed their suboptimal behaviors. Ms. Lee said that progress is mentioned in daily huddles or in person. This has not been handled through STARS. In the next phase, STARS will be opened up for patient input.

Mr. Gilman emphasized the fact that reporting increased in the first month after STARS was put in place. That is remarkable. He said that the implementation team, those who made the videos, and those who put together trainings did an amazing job.

Follow-Up Item:
- Dr. Forese requested a copy of the videos that Ms. Lee presented.

Closed Session

Dr. Forese closed the open session at 11:18 a.m.

As described in 82 FR 18660, a portion of the meeting will be closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App), and provisions set forth in sections 552b(c)(6) and 55b(c)(9)(B), 5 U.S.C.

Adjournment of Closed Session

Dr. Forese adjourned the closed session at 12:01 p.m. The open session reconvened at 1:30 p.m.

Observations and Follow-Up After the AAHRPP Reaccreditation Site Visit

Michael Gottesman, M.D., Deputy Director for Intramural Research

Dr. Gottesman explained that AAHRPP is the major nonprofit national accrediting body for human subject protection programs. The process involves an extensive application a year in advance and a subsequent site visit. NIH was fully accredited for an initial 3 years, beginning in 2014. The reaccreditation site visit occurred during December 12–16, 2016.

The four AAHRPP site visitors conducted 114 interviews with IRB chairs, IRB members, IRB support staff, and IC and Human Research Protection Program (HRPP) leaders. The site visit took 5 days.

Dr. Gottesman presented some comments from the AAHRPP report dated March 20, 2017. Positive comments were received on the expansive concept development process and scientific reviews (using the prior model), the Office of Human Subjects Research Protections, the Clinical Center's Department of Bioethics, and the National Institute of Mental Health's (NIMH's) human subjects protection unit. The report stated that the Clinical Center's patient representative and its Office of Patient Safety and Clinical Quality serve as a model for improving participant protection.

The report noted strong dedication at all levels of NIH to prioritizing exceptional patient care in the context of human participant research. The result of the site visit was full reaccreditation on March 20, 2017.

The site visitors also made some useful observations. Because of NIH's federated structure, the distribution of resources is unbalanced. HRPP was not allocated the resources necessary to carry out policies and procedures across all federated institutes.

Also, researchers said that reviews of research by convened IRBs were not being conducted in a timely manner. The AAHRPP reviewers noted that NIH IRBs used three separate computer systems and applied inconsistent review processes. As a result of these observations, the IRP is going to implement a single NIH-wide system (Integrated Research Information System, or iRIS) to manage all protocol documents. The upgraded system has been purchased and installed, and transfer of protocols is underway.

Also being implemented is the use of standardized protocol templates for scientific and IRB reviews. NIH is establishing a centralized IRB operations office to assign protocols to the reorganized IRBs and track the progress of reviews.

The IRB panels will be reshuffled along the lines of generic medicine/pediatrics or along themes. Some special panels will be assembled (e.g., epidemiology, oncology). Six IRB panels will be established, each with 7 to 13 members who meet weekly. Expedited reviews will be evaluated

and approved by IRB operations staff, IRB chairs or vice chairs, and/or designees of the chair, although panel review will remain an option.

All NIH clinical investigators will have access to protocol navigators.

The IRB changes are going to be very time-consuming, because intramural investigators are carrying out more than 2,000 protocols. Dr. Gottesman anticipated that most of these changes will be completed by the end of 2017, with full centralization accomplished by this time next year.

Discussion
Dr. Forese inquired about the vision for the IRB reorganization, say, in a couple of years. Dr. Gottesman replied that all protocols would be going through the centralized IRB operations office and assigned to one of the consolidated IRBs. All the chairs will be new and full time. IRB members will be chosen carefully, because weekly meetings will be required. The director of operations will make sure "the trains run on time." If NIH is successful in centralizing support, all investigators will have access to protocol navigators. The reorganization will be deemed a success if people find the situation an improvement over the status quo.

Dr. Shannon said this will be a difficult change to implement, but good progress has been made. He said it was very validating that an external body reviewed the Clinical Center and issued recommendations. Focusing on technology will be key.

NIH Clinical Center Department of Bioethics: Clinical Care and Clinical Research

Christine Grady, Ph.D., M.S.N., RN, Chief, NIH Department of Bioethics, Clinical Center

Dr. Grady provided an overview of the [NIH Department of Bioethics](#). Her presentation focused on the tensions between clinical research and clinical care. She gave some real-life examples from the Ethics Consultation Service.

The Department of Bioethics has four main functions:
- Provide high-quality consultation to the Clinical Center and NIH research participants
- Educate the NIH community and others about bioethics
- Conduct research on important and timely bioethical issues
- Train the next generation of bioethics scholars, educators, and consultants

The department has a very productive research program that is reviewed every 4 years by the Board of Scientific Counselors and always receives excellent reviews.

In terms of the bioethics fellowship program, the department has a highly regarded 2-year fellowship program that has trained more than 100 bioethics fellows.

Clinical research is distinct from clinical care. These two fields come into tension at the level of the investigator, the relationship with the participant, and the relationship between clinical and research teams. Clinical research and clinical care differ in their goals, methods, justification of risks, and levels of uncertainty. Clinical research relies on double blinding, rigid schedules, and randomization; in clinical care, the treatment is tailored to the patient's circumstances. Researchers often ask people to take on extra procedures to answer the research question. With research, uncertainty about outcomes is the starting point.

The tension can manifest in decisions about study design, recruitment, informed consent, procedures and monitoring, dose or intervention modification, withdrawal, and study intervention.

There are areas of overlap between care and research, however. Clinical research often includes people with illnesses who are seeking care and treatment. Individuals often do receive benefits from research, including therapeutic benefits. Quality clinical care is provided to research participants by physicians, nurses, and other health care providers in hospital settings.

The Clinical Center is unique in ethically salient ways. Investigators have an ethical responsibility to conduct clinically relevant, high-quality research. Each person who comes to NIH is a research participant. Also, high-quality patient care is a hallmark of the Clinical Center and is an ethical requirement for research.

Regarding the portfolio of Clinical Center research, about a third of protocols are clinical trials, about a third are natural history studies, and the rest involve other types of research—mainly sample data analysis, but also training and screening protocols. The level of tension varies across the research spectrum. Healthy volunteers receive some care, and natural history studies use standard treatments. The tension is most acute with interventional trials in which participants are randomly assigned to a study arm and where participants and researchers are blinded to those assignments.

The Clinical Center Department of Bioethics is not the ethics police. Rather, the department is a multidisciplinary group of doctors, lawyers, nurses, philosophers, and scientists that is integrated into the fabric of the Clinical Center. They go on clinical rounds, participate in patient safety huddles, and take part in meetings of IRBs, data safety and monitoring boards, NIH committees, and study sections. The bioethicists provide consultation in complex situations and assist with the NIH Ability to Consent Assessment Team (ACAT). Each IRB has a bioethicist as a primary voting member; this is someone who has expertise in the ethics of human subjects protection. The pilot reorganized IRB panel will be co-chaired by a member of the department.

Ethics education is an important role for the bioethicists. Ethics Grand Rounds uses cases handled through the consultation service. An outside expert provides comments, which are followed by a discussion. The Grand Rounds are webcast. The department also offers courses on research ethics. About half of participants are remote watchers. Evaluations have been positive.

The Bioethics Consultation Service is available on a 24/7/365 basis to consult on issues related to confidentiality, conflicts, and research ethics. A lead consultant and a fellow respond to all requests. The service provides written reports with an analysis and recommendations. Each year, the service handles about 140 consultations. Some require only a half-hour on the phone, but some take 3 weeks. Requests come mainly from physicians and nurses. Many consultations relate to participation in research.

ACAT was created in early 2011. Voluntary informed consent is an important concept, so the Department of Bioethics wants to be sure that people have the capacity to consent. ACAT offers an important service for safeguarding research participants with questionable capacity or without capacity. ACAT offers independent assessments to help identify an appropriate surrogate when indicated, assessment of capacity to appoint a surrogate, and assent and dissent monitoring. The department has developed a policy and standard operating procedures, assessment tools,

processes, and outcomes to identify the level of risk and the prospect for benefits associated with research participation.

Dr. Grady presented some examples from consultations. In one, the bioethics team became involved in study planning. NIMH researchers proposed a study of the neurobiology of suicide and wanted to plan how to enroll such a vulnerable group of people and whether this population would have the capacity to provide informed consent. The main factors to consider were the risk to these individuals, the ability to get them transferred from the community to NIH, and an action plan to cover the scenario in which a participant withdrew from research, in which case arrangements would have to be made for transfer and continuing care.

Another example involved a study design issue: A patient was concerned about the design of oncology studies, especially eligibility criteria for cancers with poor prognoses. To be eligible for a cancer research protocol, participants often are required to have exhausted other treatment options. This, in the patient's view, was unethical. With his cancer, he was unlikely to respond to standard therapies. An ethics Grand Rounds was presented on the case.

Another example focused on study participation, specifically the appropriateness of particular persons as research participants. There can be a tension between integrity of the science, risk to the participant, a patient's clinical needs, and the complexity of patient circumstances. For example, would it be ethical to enroll a participant who lives in a rural area without a phone, with limited social support and little money? In other examples, Dr. Grady said that a history of mental illness and substance use could make it difficult for participants to follow an intense inpatient protocol regimen. Or what about enrolling a participant with diabetes or HIV infection who is nonadherent with her primary care treatments but wishes to continue in research, or enrolling someone who is abusive to staff and resistant to procedures but has few other options for treating his disease? Treating people fairly is important, but not every person gets to be in the study. What are ethically correct reasons to keep people out of a study? Risks come from many sources. To what extent do nonclinical factors build up to justify excluding a person from research participation? Also, there is a risk of jeopardizing the research and the contributions of other participants. There is also the question of exploitation. It could be discriminatory to say that certain people are ineligible to take part in research. Difficult behavior could signal ambivalence about participation.

Another bioethics consultation had to do with clinical discharge. A child had multiple complications, including renal insufficiency and graft-versus-host disease. He was here from another country with his mother. He wanted to go home and was refusing care. The team was very conflicted. They had taken care of the child for months, and they were worried he could not get the care he needed in his home country. The study team called a bioethics consultation. The bioethicist dealt with such questions as what the team's responsibilities were and how decisions about discharge should be made. The consultants helped clarify goals and tradeoffs with the research team and then did the same with the patient and his mother.

In summary, ethical clarity can help mitigate possible tensions between rigorous clinical research, protection of research participants, and good clinical care. Paths forward can help shape research and more.

Discussion
Dr. Tuckson recommended being more explicit about the concept of risk in discussions with research participants. High-quality clinical care should be inherent in clinical research.

Investigators must be fundamentally dedicated to minimizing and preventing risk to the extent possible. These concepts are implied but are not stated explicitly.

Dr. Tuckson also recommended focusing on eliminating as many variables as possible when interpreting clinical research outcomes. If clinical care is substandard, then interpreting research results is impossible. Dr. Grady agreed on the importance of excellent patient care in interpreting the outcomes of research. Dr. Tuckson emphasized the need to enhance quality of care because of the responsibility to patients and to research.

Mr. O'Neill commented on the case in which an 11-year-old wanted to be discharged, noting that the ethicists have to decide whether the child can make an informed decision about what is in the child's best interest. If a person is in a suicidal crisis, then perhaps their judgment cannot be accepted at all. Dr. Grady said that there is a presumption that a child cannot understand what is in his or her best interest. In this particular case, further discussion revealed that the young patient really wanted to see his siblings, and NIH staff could make that happen in another way.

Clinical Center Engagement Project: Report on Clinical Center Focus Groups

Stewart Simonson, J.D., Facilitator

The Clinical Center Engagement Project is complete. Mr. Simonson reported that the report was submitted earlier in the day. Dr. Tabak informed IRP staff about the report in an email, which included a link to access the report online.

The objectives of the project were to learn from IRP staff how to enhance quality of care and to provide IRP staff with an opportunity to voice their concerns about the Clinical Center.

Methodology
Seventy focus groups were conducted between September 2016 and January 2017, in addition to numerous meetings and small group discussions.

Focus groups addressed five questions:

1. What is great about the Clinical Center?
2. What tensions do you observe between patient care and clinical research?
3. How, if at all, does the unusual organizational structure of the Clinical Center affect patient care?
4. What concerns related to patient safety weigh on you?
5. If you could change one thing about the Clinical Center to improve patient safety, what, if anything, would you change?

Each group was very different, but all were prepared and constructive. The participants were self-selected. The focus groups were highly inclusive (ranging from physicians to housekeepers to vendors to nutrition staff and more). Drafting of the report began immediately after the final focus group session in January.

Mr. Simonson synthesized the focus group discussions into themes. He then synthesized 50 recommendations that addressed or otherwise responded to these themes. He consulted with the Clinical Center Engagement Working Group about the themes and while drafting the report.

Mr. Simonson said the responses to the context-setting question about what makes the Clinical Center great were quite moving. Staff commented on how meaningful it was for them to be part of groundbreaking research. They experience a genuine connection with patients and families. They feel privileged and honored to work at the hospital that literally has no peer.

Findings and Recommendations
Five themes emerged. They are listed here, along with some common observations by the focus groups and examples of relevant recommendations:

1. Governance, administration, and accountability

   a. The organization is fragmented and stove-piped.

   b. There is a lack of a comprehensive strategic plan for the Clinical Center.

   c. The CEO has limited authority over activities of the NIH Office of the Director (OD) and the ICs in the Clinical Center.

   d. Broader representation of staff involved in day-to-day patient care on the MEC is needed.

   Recommendations:

   - *Develop a comprehensive, multiyear strategic plan for the Clinical Center. Then produce funding streams to fund the strategic plan initiatives.*

   - *Delegate to the Clinical Center CEO authority over all activity affecting clinical care, whether performed by NIH OD or IC staff.*

   - *Obtain formal input from the Clinical Center CEO for annual performance assessments of Institute Directors with programs at the Clinical Center and certain NIH OD staff. It will be important, as the Clinical Center is really the place where the 17 ICs do their work. The CEO needs to have input on their performance.*

   - *Review the organization and membership of the MEC to give better representation to staff involved in day-to-day patient care.*

2. Quality of care and clinical research

   a. The Clinical Center is not a general hospital. There are real limitations on its capabilities in some clinical areas.

   b. There is sometimes tension between the applicable standard of care and the research protocol.

   c. Support provided to clinical investigators is uneven and, in some cases, suboptimal. For example, some ICs provide access to protocol navigators, and others do not. The level of support for investigators should be consistent across the Clinical Center.

   Recommendations:

   - *Commit funding to enhance services provided by ICs at the Clinical Center (e.g., hospitalists).*

- *Develop a Clinical Center–wide process to address differences of opinion when the applicable standard of care conflicts with or does not align with the research protocol.*

- *Commit funding for enhanced and uniform support of clinical researchers.*

3. <u>Communications and engagement</u>

   a. Information sharing is uneven within the Clinical Center. Much was heard on this topic during the focus groups.

   b. In particular, the identification of and communication with the responsible medical provider is sometimes problematic at the Clinical Center.

   c. Engagement of staff has been uneven and suboptimal.

   Recommendations:

   - *Consult with staff to find out what they need from the CEO.*

   - *Hold quarterly town hall meetings and quarterly M&M conferences.*

   - *Develop and fund unified telecommunications, policies, and processes for all patient care staff in Building 10.*

4. <u>Organizational development and human resources</u>

   a. Succession planning is inconsistent and underdeveloped, leading to vulnerabilities for key positions.

   b. Non–tenure-track staff feel undervalued. They provide a significant part of the clinical care but do not always have access to professional development and other valued clinical training.

   c. The human resources process is slow and unresponsive.

   Recommendations:

   - *Establish and fund professional development, and develop succession plans for key positions and functions at the Clinical Center.*

   - *Undertake an assessment of human capital requirements for the Clinical Center.*

   - *Establish and fund a mechanism to recognize and reward non–tenure-track staff.*

   - *Intervene at the highest levels of HHS and the Office of Personnel Management to improve human resources support for the Clinical Center.*

5. <u>Clinical Center facilities, equipment, and systems</u>

   a. Older parts of the Building 10 complex are showing their age and need renovation or replacement.

   b. Essential equipment is showing its age and needs to be replaced. Cannibalization of equipment to obtain replacement parts is common.

   c. Support functions at the Clinical Center (e.g., housekeeping) have insufficient management information systems.

- *Address immediate and urgent facilities needs for the Clinical Center Department of Perioperative Medicine, Department of Transfusion Medicine, Department of Laboratory Medicine, PET imaging, and radiology and imaging systems.*

- *Undertake a review of essential equipment vulnerabilities, and replace equipment that is past its useful life.*

- *Undertake a review of management information needs for Clinical Center support functions, and invest accordingly in systems for these functions.*

Conclusions

The overarching message of the project is that the Clinical Center is a great research hospital, but it is not perfect. There are areas in need of improvement. The project took a year. During that time, good progress already has been made. Essential facilities are being repaired and renovated. Quarterly town hall meetings and M&M conferences are being convened, ORS has been replaced by STARS, a process has been put in place to improve succession planning, and Dr. Gilman has been hired as CEO.

In closing, Mr. Simonson said he is very optimistic about the future of the Clinical Center and that it was an honor for him to be a part of this important work. The willingness of NIH leadership to undertake a self-critical project bodes well for the future. Mr. Simonson thanked Dr. Collins for asking him to take on the project.

Discussion

Dr. Collins thanked Mr. Simonson for undertaking the project as a volunteer, particularly because he was also managing a hospital in Haiti. Dr. Collins thanked Stuart Nightingale, M.D., and the staff who contributed to this effort. Dr. Collins also appreciated Mr. Simonson's regular briefings of NIH leadership, which made it possible to start taking action even while the focus group sessions were still going on. Dr. Gilman came on board as CEO to initiate some of the many recommended changes. It is gratifying to see Mr. Simonson's hard work propelling the Clinical Center to an even greater status.

The recommendations will continue to guide us and strengthen the role of this house of hope. Some recommendations are within NIH's locus of control, but some would require assistance from other entities. For example, the hiring freeze means that NIH cannot fill all open positions, most notably the human resources position.

Dr. Shannon thanked Mr. Simonson for his efforts and the NIH staff for their willingness to be transparent and open and set the Clinical Center on the next phase of its journey of continuous improvement. He pointed out that this report could have been describing the situation at many health care institutions. Many of the themes, including uneven support of investigators and nontenured staff's feelings of being undervalued, are true everywhere. The Clinical Center is unique, however, because the staff care for patients with rare, complex illnesses, and that care is overlaid with world-class research. Undoubtedly, defects and errors will still occur, but the report puts the Clinical Center on a new trajectory regarding improvement.

Mr. Simonson noted that the Clinical Center also differs from other health care facilities because it is not subject to reimbursement or tort systems. However, the Clinical Center is subject to a

different type of risk that is hard to calibrate: political risk. The lack of a comprehensive strategic plan strikes Mr. Simonson as a high-priority gap that needs to be addressed.

Dr. Pronovost remarked that the project was the result of very impressive and thoughtful work. The report reflects challenges present in any complex organization or leading medical center. "We are often so focused on the output of discovery that we do not take time for internal reflection to make sure the home organization is productive, nurtured, maturing, and given constant attention," Dr. Pronovost said. Systems, culture, and structures are now being put in place to provide a lens for reflection and introspection. The infrastructure now seems to be in place.

Dr. Pronovost also observed that academics and researchers often think there is a conflict between good care and biomedical discovery. But, they go together: Improvements in patient safety strengthens research, and this report could be the impetus for such improvements.

Mr. O'Neill was enthusiastic about Ms. Lee's report on STARS. The NIH Clinical Center is demonstrating that it is responding to insights and comments. Going forward, the Clinical Center will have a common framework in place for information flow. Mr. O'Neill asked whether sufficient information flow opportunities are in place so the leadership has the necessary dialog to establish a self-energizing process to keep moving forward and whether such a mechanism exists underneath what is happening now. Mr. Simonson agreed with the importance of effective information flow, and he thought that the systems were not fully in place. He emphasized the need for having a renewal process to avoid the future need for additional snapshots, such as the one provided by this project. He also reiterated the need for a multiyear strategic plan that brings in the ICs, the OD, and Drs. Gilman and Gallin.

Mr. Simonson said that the most important action will be getting Drs. Tabak, Gilman, Gallin (and others) at a table with the 17 IC Directors to deal with problems, such as low census. A serious and actionable dialog must occur with stakeholders and providers in the hospital to reach consensus about the vision for the Clinical Center and how it will achieve its goals.

Dr. Gilman said that in the military, "plans are nothing, but planning is everything." He supported the idea of strategic thinking, a term that was used in a session with Clinical Center staff. A second meeting will be held on July 31, 2017. Starting in August, people from the ICs will get involved. If a decision is made to create a strategic plan, it will be a living document for looking ahead 3 to 4 years. Some factors will change in terms of budget and research needs, but some things, such as continuous improvement in the care we provide and improvement in the systems so we can strive for high reliability, will not change. "Strategic thinking and strategic planning are paramount, but it is always good to have a document as a focus," said Dr. Gilman. Dr. Pronovost said that the structure for those conversations will be key.

Dr. Forese added her thanks to Mr. Simonson for the successful completion of this project.

Follow-Up Item:

- Even more critical than a strategic plan is a *strategic thinking process*. This could be made clearer in the report.

Closing Statement and Adjournment

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

Dr. Forese closed the fifth meeting of the CCRHB by saying that great progress has been made: Foundations have been laid, and dialogs are ongoing. She thanked the presenters and said she looks forward to the phones lighting up in response to the documentary about the Clinical Center. She and Dr. Collins thanked the Board members for their thoughtful input.

The next face-to-face CCRHB meeting is scheduled for October 20, 2017.

Dr. Forese adjourned the meeting at 3:06 p.m.

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

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

_____

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

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

AAHRPP	Association for the Accreditation of Human Research Protection Programs, Inc.
ACAT	Ability to Consent Assessment Team
CCE	Center for Cellular Engineering
CCGB	Clinical Center Governing Board
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CNE	chief nursing executive
CNO	chief nursing officer
CT	computed tomography
DDIR	deputy director for intramural research
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
FMEA	failure mode and effects analysis
FY	fiscal year
GMP	Good Manufacturing Practices

HHS	Department of Health and Human Services
HRPP	Human Research Protection Program
ICs	Institutes and Centers
IND	Investigational New Drug (application)
IRB	institutional review board
iRIS	Integrated Research Information System
IRP	Intramural Research Program
MEC	Medical Executive Committee
M&M	Morbidity & Mortality (Conference)
MRI	magnetic resonance imaging
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIDCD	National Institute on Deafness and Other Communication Disorders
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
OD	NIH Office of the Director

ORS   Occurrence Reporting System

PET   positron emission tomography

PSCPQC   Patient Safety, Clinical Practice, and Quality Committee

SEEC   Seeking Equality, Empowerment, and Community for People with Developmental Disabilities

STARS   Safety Tracking and Reporting System