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

Third Meeting of the
Clinical Center Research Hospital Board

January 13, 2017

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Clinical Center Research Hospital Board

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Ruth Brinkley, R.N., M.S.N., FACHE, Senior Vice President, Catholic Health Initiatives; President and CEO, KentuckyOne Health

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

Executive Summary

The third meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on January 13, 2017, on the NIH main campus. The meeting was open to the public and was webcast live. Laura Forese, M.D., Chair, CCRHB, welcomed all those in attendance. Dr. Forese introduced Major General James K. Gilman, M.D., the inaugural chief executive officer of the NIH Clinical Center (NIH CC).

Francis S. Collins, M.D., Ph.D., NIH Director, thanked Dr. Forese for her outstanding leadership of the CCRHB. He welcomed Dr. Gilman and thanked him for his willingness to help the Clinical Center reach its full potential. Dr. Collins also thanked John Gallin, M.D., NIH Associate Director for Clinical Research and Chief Scientific Officer at the Clinical Center, for his more than two decades of service as the Clinical Center director.

Dr. Gilman summarized his experience and described his immediate focus areas: creating a seamless transition of responsibilities, patient safety, the NIH CC pharmacy, employee/staff engagement, and information operations. His near-term focus areas include assembly of the leadership team, revision of the organizational chart, facilities, and communication of priorities.

Stewart Simonson, J.D., Facilitator, Clinical Center Engagement Group, provided an update on Clinical Center staff focus groups that he facilitated from September 2016 – January 2017. He summarized focus group comments/issues and draft recommendations to address these issues.

Michael Gottesman, M.D., Deputy Director for Intramural Research, reported on the findings from a survey of late reporting of serious adverse events (SAEs) and unanticipated problems (UPs) in NIH-sponsored studies to sponsors and institutional review boards (IRBs). The results showed that 60% of events that should be reported to the IRB on an expedited basis (UPs and SAEs) were reported late, as were 17% of SAEs and UP/SAEs that should be reported to the sponsor. Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, and Executive Director, CCRHB, described the many steps that NIH is taking to address these findings. These actions include an independent audit by a clinical research organization, cross-checks of event reporting, site visits, and communicating to investigators the consequences of poor compliance.

Laura Lee, R.N., M.S., Chief, Patient Safety and Clinical Quality, Clinical Center, presented data on rates of whole-house central line-associated bloodstream infection rate at the Clinical Center, which have declined after interventions were implemented to address the increase in these infections in 2015. She described Clinical Center activities to address patient safety issues, including daily safety huddles and a patient safety event reporting system. Ms. Lee also described the activities of the Trigger Tool Harm Investigation Working Group, which conducts intensive analyses of cases identified by a range of pre-identified triggers.

The presentation by Michele R. Evans, Dr.P.H., Environmental Safety Officer, Clinical Center, focused on proactive measures at the Clinical Center to prevent occupational injuries and illnesses, including reviews of worker safety with all new employees, policies and procedures to manage workplace hazards, and workplace risk assessments. Dr. Evans also described approaches to reduce the number of musculoskeletal injuries, which account for about half the reported occupational injuries and illnesses at the Clinical Center in 2016.

Andrea Norris, M.B.A., Director, Center for Information Technology; Chief Information Officer, NIH, detailed the cybersecurity challenges that NIH faces and how it responds to and prevents security threats to its information technology. She also described potential vulnerabilities to NIH cybersecurity and the multifactorial approaches that NIH takes to provide the needed protection.

Dr. Gallin presented average daily census data for the Clinical Center in fiscal years 2013–2017 (to date), which have declined. Dr. Gallin discussed the causes of this decline, such as laboratory closures and the replacement of departing principal investigators with newer and less experienced investigators. Stephen Katz, M.D., Ph.D., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases, listed immediate, near-term, and longer-term recommendations to increase the Clinical Center's census developed by the Clinical Center Governing Board Working Group on Clinical Center Utilization.

Dr. Tabak delivered an update on NIH sterile and non-sterile processing facilities. He reviewed the function and status of each of these facilities along with all remediation and construction activities that are underway or planned.

Dr. Forese and Dr. Collins thanked the board members for their thoughtful input. Dr. Forese adjourned the open session.

The next face-to-face CCRHB meeting is scheduled for April 28, 2017.

<h1 style="text-align:center">Meeting Summary</h1>
<h1 style="text-align:center">Friday, January 13, 2017</h1>

Welcome and Overview of the Board Chair

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

The third meeting of the NIH CCRHB took place on January 13, 2017, on the NIH main campus. The meeting was open to the public and was webcast live. Dr. Forese called the meeting to order at 8:34 a.m.

Dr. Forese introduced Major General James K. Gilman, M.D., the inaugural chief executive officer (CEO) of the NIH Clinical Center. The CCRHB's primary duty was to ensure that an outstanding individual would be appointed to lead the NIH Clinical Center, and the board has accomplished this goal. Dr. Gilman is a cardiologist with many years of distinguished service in the U.S. Army and experience in all sectors of health care. Dr. Forese welcomed Dr. Gilman on behalf of the CCRHB. She also thanked John I. Gallin, M.D. for his many years of distinguished service to the NIH Clinical Center and welcomed him to his new dual role as NIH Associate Director for Clinical Research and Chief Scientific Officer, Clinical Center.

NIH Director's Remarks

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

Dr. Collins thanked Dr. Forese for her outstanding leadership of the CCRHB and the CCRHB members, who advise NIH in a wide variety of ways. Their willingness to accept this invitation and spend their time on these important issues gives Dr. Collins great hope that NIH is on the right path to make a superb hospital into an even finer place.

Dr. Collins welcomed Dr. Gilman and thanked him for his call to service and his willingness to help the Clinical Center reach its full potential. The CCRHB is available to provide the support and advice that Dr. Gilman needs.

Dr. Collins extended a special thank you to Dr. Gallin for his more than two decades of service as the Director of the NIH Clinical Center, during which Dr. Gallin presided over a variety of major triumphs, including the Clinical Center's receipt of the Lasker-Bloomberg Public Service Award in 2011. Dr. Collins looked forward to Dr. Gallin's leadership in his new dual role as NIH Associate Director for Clinical Research and Chief Scientific Officer, Clinical Center.

Remarks from the Clinical Center CEO

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

Dr. Gilman summarized his professional experience, which includes 35 years in the U.S. Army in clinical care, teaching, and hospital executive leadership. In his last 4 years there, he oversaw all medical research and development for the U.S. Army, and he then spent 3 years as the executive director of the Military Health Institute at Johns Hopkins University.

Dr. Gilman's immediate focus areas include creating a seamless transition between Dr. Gallin's responsibilities and his own, patient safety, and the Clinical Center pharmacy. He has also begun engaging Clinical Center staff by scheduling a series of "meet the CEO" sessions for workers on

various shifts. Efforts to address the final immediate focus area, information operations, will include keeping NIH leadership fully informed of items of special interest as they arise.

Near-term focus areas:

- Patient safety – This issue will remain a high priority for the foreseeable future.
- Assembly of the leadership team – Efforts will be made to address safety issues in an interdisciplinary way.
- Revision of the organizational chart
- Facilities – A challenge is the need to create good manufacturing practice (GMP)–compliant facilities in the oldest part of the Clinical Center.
- Communication of priorities

Patients are the most important people in the NIH Clinical Center. Taking care of those who work for the Clinical Center is also important. Other priorities are inclusion of diverse perspectives, development of young leaders with academic expertise and appropriate skills, and stewardship.

Discussion
Group discussion focused on the following issues:

Praise and Expectations for Dr. Gilman
- Peter Pronovost, M.D., Ph.D., commented that Dr. Gilman's agenda is consistent with that of Dr. Collins and characterized Dr. Gilman as a "quick study." Carolyn Clancy, M.D., saluted Dr. Gilman for the "meet the CEO" sessions that are scheduled to accommodate all staff schedules.
- Brig. Gen. James Burks, M.B.A., M.A., FACHE, agreed that Dr. Gilman's job is to articulate Clinical Center needs regardless of funding considerations, which is a better way to move the center forward than starting with the amount of money available. He also noted his support for Dr. Gilman's stated priorities.
- Beatrice Bowie expressed her pleasure at Dr. Gilman's arrival and predicted that he will be a great asset to NIH. She was pleased that patient engagement is a top priority.

CEO Engagement Strategies
- Dr. Forese asked how Dr. Gilman will approach patient groups. Dr. Gilman replied that to be more operationally relevant, the NIH Patient Advisory Group should meet more frequently and add new Clinical Center patients to its current members. The group should also be critical of NIH when necessary to maximize the group's effectiveness.
- Reed Tuckson, M.D., asked whether Dr. Gilman plans to meet with each NIH Institute and Center (IC) director. Dr. Gilman replied that he has already started meeting with the directors of the 17 ICs that sponsor research at the Clinical Center. Dr. Collins added that Dr. Gilman and Dr. Gallin attend IC Directors' meetings, some of which include discussions on the Clinical Center.

Continued Role of the CCHRB
- Dr. Forese said that some changes are about to take place at the Clinical Center, and the CCRHB will want to monitor them. The board's role is to continue to be supportive and ask some tough questions.

Clinical Center Focus Groups

Stewart Simonson, J.D., Facilitator, Clinical Center Engagement Group

Mr. Simonson provided an update on the 70 focus groups with 621 Clinical Center staff members that he facilitated between September 2016 and January 2017. Participants comprised a broad range of staff, including physicians, nurses, dentists, pharmacists, social workers, and bioethicists. The questions that the focus groups answered are available in the presentation slides online at https://ccrhb.od.nih.gov/presentations/01132017_CCFocusGroups.pdf.

The discussions have been grouped into seven themes:

- Commitment and mission
- Governance and accountability
- Fragmentation and inconsistency
- Communications and engagement
- Organizational development and human resources
- Clinical Center facilities
- Resourcing and risk management

Next steps are to present the draft summary of discussion themes and recommendations to the Clinical Center Engagement Working Group for review and approval, brief Dr. Gilman and the Clinical Center Medical Executive Committee on the approved summary, and submit the final summary to the Clinical Center Steering Committee by March 1.

Mr. Simonson shared a story from a focus group participant who said that in spite of all the things that need to be improved at the Clinical center, the staff member would want his daughter treated at the Clinical Center if she were ill. After 70 focus groups and many interviews, Mr. Simonson feels the same way. He hoped that the focus group process will result in sustainable solutions to the manageable, solvable problems at this great hospital.

Discussion

Group discussion focused on the following issues:

Incorporation of Focus Group Data into Clinical Center Operations
- Dr. Forese thanked Mr. Simonson for this enormous undertaking and asked what he might do differently with future focus groups. Mr. Simonson said that he would organize more focus groups for specific functions and ask participants to make a greater commitment to attend. He hopes to make the focus groups a regular feature of the Clinical Center.
- Brig. Gen. Burks noted the passion for the Clinical Center that Mr. Simonson and focus group participants had expressed is very encouraging. He also noted the congruence between the comments from diverse focus group members and Dr. Gilman's priorities. Brig. Gen. Brooks supported the recommendation for a strategic plan. Once the plan is in place, the next step is to align resources for accomplishing the plan's objectives. The Clinical Center leaders might consider seeking external assistance with the strategic planning process.
- Dr. Pronovost was also struck by the immense passion and commitment to the Clinical Center's mission from its employees. The Clinical Center's leaders will need to ensure that the wealth of information from the focus groups is integrated into the center's operations.
- Dr. Tuckson said that the CCRHB must be consistent in its support for change and called on the Clinical Center's management to rapidly incorporate the recommendations from the focus

groups into a strategic plan. He also encouraged Mr. Simonson and his team to connect each comment and theme to a recommendation. Mr. Simonson explained that some comments absent from the recommendations will be addressed during the strategic planning process.

- Ms. Brinkley commented on the importance of managing expectations by establishing priorities, because it will not be possible to accomplish everything listed. Quickly implementing even one or two of the focus groups' recommendations would show the importance of the groups' contributions. It will be advisable to communicate exactly which changes staff should expect, when those changes will occur, which changes will not be made, and what is going well at the Clinical Center.

Staff and Participant Motivations

- Mr. Simonson noted that the staff's commitment and dedication to patients extends throughout the organization. As an example, he shared stories from kitchen staff about their efforts to cook familiar foods for patients from other countries.
- Richard Shannon, M.D., noted the remarkable efficiency of this engagement of employees across the organization and the process of choosing a new CEO. These experiences provide evidence of the organization's exceptional capabilities. He also noted that although one focus group comment was that patients come to the Clinical Center to advance medical science, the real reason is that the patients need access to highly specialized expertise for very rare diseases and that more common diseases need new approaches; as a result, patients' treatment at the Clinical Center advances medical science. It is important to phrase this information appropriately.
- Dr. Pronovost pointed out that patients come to the Clinical Center for hope, and suggested this concept as one that all employees could rally around.

Communication of Focus Group Results and Clinical Center Changes

- Ellen Berty suggested that Mr. Simonson share the focus group results with Clinical Center staff and patients. Mr. Simonson said that the focus group results will be posted on the Clinical Center's website, and his presentation slides and the final report will be available to staff. Dr. Collins pointed out that this meeting was open to the public.
- Dr. Forese noted the need to share the positive news from the Clinical Center with all constituencies, including the public, patients, providers, and those who are so proud to work at the center. Dr. Tuckson emphasized the importance of being diplomatically cautious in talking to various stakeholders about the Clinical Center's future while being impatient and demanding rapid change. Although this balance is important, it might be advisable to err more toward impatience.

Additional Collection of Input

- Dr. Shannon recommended measuring staff engagement across the organization, possibly using a survey. He approved of the suggested adoption of appropriate Centers for Medicare & Medicaid Services (CMS) patient safety and quality requirements, but noted it should not be bound by the CMS requirements, because of its unique mission and lack of claims data. He suggested that the Clinical Center focus on measures that matter to patients and define itself in terms of its clinical outcomes.
- Dr. Forese proposed that the Clinical Center implement a formal employee engagement survey, which can offer rigor. Dr. Shannon explained that the power of such a survey is the ability to compare the organization with other organizations and that finding the right comparator for the Clinical Center would be challenging. However, a survey could be used to

mark progress over time.
- Dr. Clancy supported the suggestion for a staff survey and proposed that the survey track whether staff feel comfortable reporting problems. The issues raised in the survey will need "relentless attention" for several years.

Dr. Collins thanked Mr. Simonson for leading this effort as a volunteer while handling his other major responsibilities. Mr. Simonson's presentation captured opportunities for improvement and the passion of the Clinical Center's staff. The Clinical Center has a dedicated cohort of care providers at all levels who believe in the center and want to make it into the most amazing place it can be in every way.

Audits of Delayed Reporting: Self-Audit Results and Formal Audit Planning

Michael Gottesman, M.D., Deputy Director for Intramural Research
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, and Executive Director, CCRHB

Dr. Collins explained that this session would address the continued efforts at NIH to identify areas where the Clinical Center is not complying with the wide variety of requirements related to patient safety, research conduct, and patient care. This effort began with a clinical trial testing a combination therapy that included ibrutinib for primary central nervous system lymphoma. Four of the trial's 18 participants developed invasive aspergillosis, and two deaths were attributed to this infection. The study's principal investigators (PIs) did not report these events to the institutional review board (IRB) and study sponsor within the required timeframe.

This session reports the results of an NIH survey asking PIs about these types of adverse event reporting delays. The results are tentative, but show that the problem is not confined to a single protocol or IC. This is a serious issue, and NIH would like the CCRHB's input on how best to address it.

Dr. Gottesman explained that although the ibrutinib trial for central nervous system lymphoma was successful, the reporting of the unanticipated problems (UPs) and serious adverse events (SAEs) to the IRB was significantly delayed. As a result, the Food and Drug Administration (FDA) issued a Form 483 about the reporting problem, and NIH leaders wondered whether this problem might be systemic.

The definitions of adverse event (AE), SAE, and UP are available at https://ccrhb.od.nih.gov/presentations/01132017_TimelyReportingProblemsNIHResearchProtocols.pdf. Generally, PIs must report SAEs in FDA-regulated clinical trials as soon as the PIs become aware of them; non-serious AEs should be reported to the IRB annually. PIs must also report all UPs and all SAEs that are UPs (SAEs/UPs) to the IRB promptly. All NIH investigators are supposed to be aware of these requirements.

The clinical directors at each IC were asked to report on the timeliness of their SAE reports for clinical studies involving interventions to sponsors and SAEs/UPs to IRBs. The data are self-reported, but they provide evidence that a problem exists: 274 of 711 eligible protocols at 15 ICs involved at least one event that was reported late. Altogether, 60% of events that were reportable to the IRB on an expedited basis (UPs and SAEs/UPs) were reported late, as were 17% of SAEs and SAEs/UPs that were reportable to the sponsor on an expedited basis.

Dr. Tabak described several steps that NIH is taking to respond to the survey results:

- Arrange for a clinical research organization to conduct an independent audit in a uniform way, to be completed by late 2017
- Perform daily or weekly rounds for prompt recognition of reportable events, likely in combination with safety rounds
- By February, establish standard operating procedures for each IC to monitor proper and timely reporting, to be followed by periodic reviews and audits to ensure that these procedures are implemented
- By March, begin cross-checking event reporting to the IRB, sponsor, and/or the FDA
- By March or April, develop an educational campaign to ensure that all staff understand their roles in reporting events
- Conduct site visits for all studies to ensure that all team members are aware of protocol procedures and reporting requirements;
- Remind IRBs of their authority to detect and report events
- Modify performance plans for IC leaders, PIs, research nurses, and other team members to include benchmarks for tracking and timely reporting of events (will be incorporated into 2017 midyear reviews)
- Articulate to PIs the consequences of continued poor compliance, which could include meetings with the Medical Executive Committee, IC leadership, and/or with Dr. Collins or Dr. Tabak

Given the complexity of trials, every PI needs access to a protocol navigator. NIH is considering whether to maintain this resource at ICs or provide navigators centrally through the Clinical Center. Every protocol also needs a compliant electronic database, and NIH will develop a single protocol tracking system across the Clinical Center by the end of 2017.

The longer-term action plan includes centralizing clinical research support (e.g., protocol navigators, quality control, monitoring) to the largest ICs with direct oversight by a single service center and reorganizing IRBs with central governance and management.

Discussion
Group discussion focused on the following issues:

PI Motivations and Responsibilities for Reporting
- Dr. Tuckson asked about PIs' motives for not reporting UPs and SAEs/UPs in a timely way. Dr. Gottesman said that the reasons can include lack of time to submit the reports, confusion about reporting requirements, and lack of an electronic reminder system. Andrew Griffith, M.D., Ph.D., Deputy Director for Intramural Clinical Research, Office of Intramural Research, and Scientific Director, National Institute on Deafness and Other Communication Disorders, added that whether an SAE or UP is related to a study is not always clear, and PIs, who must sign and submit the reports, sometimes are away and cannot do so. In his experience, PIs do not intentionally fail to report events.
- Dr. Pronovost emphasized the need to both ensure that researchers see their work through a safety lens and strengthen accountability mechanisms. In addition, NIH should create a peer learning forum to share best practices.

Agency Responsibilities for Promoting a Culture of Reporting
- Dr. Forese expressed surprise and disappointment that this research requirement is not being met and said that the high rate of noncompliance speaks to the culture of reporting

at NIH. It is important to develop fixes for some of the personnel issues, such as having backup systems for signing and submitting reports when PIs are away.
- Dr. Tuckson said that in addition to the consequences of late reporting that Dr. Tabak mentioned, NIH should consider "hardball" penalties, such as economic sanctions or dismissal. At the same time, the NIH culture must create a safe harbor for reporting compliance failures and encourage reporting.

Additional Reporting and Analysis Suggestions
- Ms. Brinkley asked whether root cause analyses are routinely conducted and recommended informing investigators of the implications of late reports beyond patient safety. Dr. Griffith said that root cause analyses are done informally.
- Dr. Pronovost asked whether NIH plans to repeat this audit and bring the results back to the CCRHB. He suggested that each IC create its own improvement plan and discuss these plans with the other ICs collectively. Dr. Griffith explained that NIH has asked each IC to submit an improvement plan. Dr. Tabak added that the purpose of the initial audit was to provide baseline data and that NIH will continue the audit to measure progress.
- Dr. Clancy asked how NIH informs patients when an event occurs, and suggested that NIH set up a hotline to report problems anonymously. Dr. Griffith said NIH's approach to informing patients of events depends on the protocol and Dr. Tabak explained that NIH does have a hotline.
  - Dr. Forese encouraged NIH to publicize the hotline now that NIH is aware of the extent of the problem. Although plans for addressing the issue are still being developed, the hotline can be a part of the interim steps NIH is taking right now.

Follow-Up Items
- The Board requested regular updates on the audits of delayed reporting.

Clinical Center Patient and Worker Safety Metrics
Performance Metrics
Laura Lee, R.N., M.S., Chief, Patient Safety and Clinical Quality, Clinical Center

Ms. Lee said that the whole-house central line–associated bloodstream infection (CLABSI) rate at the Clinical Center increased in the last quarter of 2015, due to a product used for line management and to inconsistencies in line care by nursing and clinical staff. After the Clinical Center implemented interventions to address these issues, the CLABSI rate improved in 2016. However, two patients did experience a CLABSI in the last quarter of 2016.

When it identifies a CLABSI, NIH conducts an intensive root cause analysis to identify, in real time, the practice or systems issues that might contribute to the infection. The nursing leadership of the patient care unit convenes the staff involved in the patient's care to review the care the patient received. Findings from the two 2016 root cause analyses are available at https://ccrhb.od.nih.gov/presentations/01132017_ClinicalCenterPatientAndWorkerSafetyMetrics .pdf.

In response to the CCRHB's suggestion, the Patient Advisory Group met with Ms. Jones, Dr. Gallin, and Ms. Lee to address their safety concerns as well as the safety and quality metrics that are important to patients. The group asked the Clinical Center to communicate with patients and the public on a regular basis about the Clinical Center's quality and safety efforts. The Clinical Center plans to encourage patient engagement in its quality improvement projects and hospital

committees. For example, the Clinical Center will soon post quality and safety "checkup boards" throughout the hospital.

The Clinical Center is also addressing safety issues through activities such as daily safety huddles, where staff from every department and most ICs quickly review safety issues from the last 24 hours and actions to prevent safety problems, and implementing a new patient safety event reporting system that includes receiving, tracking, and responding to reports from the anonymous reporting hotline. Issues reported in recent months include lack of availability of cytogenetic testing, environmental hazards, and poor air quality.

The Clinical Center's Trigger Tool Harm Investigation Working Group, which is helping the Clinical Center learn about risks and harms in the center's environment, received the NIH Clinical Center Director's Award for Patient Safety Leadership. The working group reviews clinical cases and identifies trends and themes in care-related issues.

Since January 2016, the working group has chosen 59 cases (from intensive care unit admissions) for intensive analysis. Of the 28 cases involving preventable harms, 21 were expected (deep-vein thrombosis, pulmonary embolism, postoperative infection, and bacteremia) and 7 were unexpected (bowel perforation with abscess, recurrent postoperative infection, fluid overload, medication interaction, and delayed palliative care procedure). Several improvement strategies were deployed, including medical morbidity and mortality rounds on recognizing early signs of sepsis (which drew 250 attendees), development of perioperative anticoagulation guidelines, and discussion of an infectious disease consult clinic for patients with long-term infections.

Finally, Ms. Lee discussed steps that the Clinical Center has taken to enhance communication with staff about safety and quality issues. NIH launched the *NIH Clinical Safety Rounds*, a biweekly newsletter sent to all clinical staff. Additionally, each IC now has a patient safety and quality liaison who is the primary point of contact for all patient safety and quality issues.

Discussion
Group discussion focused on the following issues:

Communication of Safety Activities within the Clinical Center
- Dr. Tuckson asked whether NIH evaluated the morbidity and mortality rounds on recognizing early signs of sepsis. Ms. Lee said that invitations were initially sent to staff who deal with patients who experience sepsis, but news of the event spread by word of mouth (resulting in high attendance). The event went very well, and the Clinical Center is likely to expand the invitation list for future events. Dr. Tuckson recommended that the Clinical Center identify a core group of people who should come to all these events, such as those providing direct patient care. Ms. Lee suggested that fellows and Clinical Center leaders also attend. Dr. Forese proposed that NIH videotape these sessions.
- Dr. Shannon said that the Clinical Center will need to develop a common problem-solving approach that all personnel understand and a common language that staff can use to report on their work processes. When each safety huddle ends, some Clinical Center leaders should visit the unit with the problem to understand what happened.

Safety Leadership
- Brig. Gen. Burks emphasized the need to involve both front-line clinical leaders and non-clinical leaders in efforts to increase patient safety, as all staff can affect patient care.

- Dr. Pronovost asked how the Clinical Center will define the knowledge and skills that the new patient safety and quality liaisons will need. Ms. Lee explained that the liaisons receive basic patient safety and quality training and will attend clinical performance metrics training programs.

Follow-Up Items
- The Clinical Center will add high-intensity antibiotic regimens to the list of triggers for intensive review by the Trigger Tool Harm Investigation Working Group.

Occupational Injuries and Illnesses: Managing Risks
Michele R. Evans, Dr.P.H., Environmental Safety Officer Clinical Center

Dr. Evans uses the following proactive measures to prevent occupational injuries and illnesses:
- Reviewing worker safety, including workers' rights and responsibilities, with all new employees
- Planning, constructing, renovating, and maintaining environments that meet occupants' needs and national codes and standards
- Communicating workers' concerns to stakeholders and leadership
- Developing and implementing policies and procedures to manage workplace hazards
- Providing institutional and job-specific education and training
- Performing complete systematic and systemic workplace risk assessments to identify chemical, biological, radiological, or physical hazards
- Conducting "environment of care" tours throughout the hospital
- Assessing occupational risks associated with new technologies
- Maintaining and applying knowledge and best practices

Employees with an injury or symptoms are encouraged to visit the Occupational Medical Service, where they can undergo timely medical review and triage. Results are documented and shared with authorized staff, and action is taken to mitigate the hazard.

As the Clinical Center's environmental safety officer, Dr. Evans relies on a variety of surveillance activities by different groups to maintain workplace safety. Dr. Evans looks for issues that require immediate attention and any trends of concern. A root cause analysis is conducted for high-risk near misses and sentinel events, and corrective actions are audited for sustainability and effectiveness.

The Clinical Center had lower rates of total and other recordable cases in fiscal year (FY) 2016 than other hospitals nationwide in 2015, but slightly higher rates of days away from work and days of job transfer or restriction. At the Clinical Center, musculoskeletal trauma accounted for 47% of all occupational injuries and illnesses reported to the Occupational Medical Service, 86% of days away from work, and 76% of days of job transfer or restriction.

A multifactorial approach (including renovations, installation of permanent lifts for patient transfers, enhanced programs and practices to reduce patient falls, and increased awareness of proper body mechanics) reduced the number of musculoskeletal injuries during patient transfers at the Clinical Center by 50% in 2016. Other efforts are underway to prevent musculoskeletal trauma not involving patient contact by mitigating pedestrian trip hazards, removing and/or adjusting tension on door closures, and revisiting options for chairs with wheels. The Clinical Center is also optimizing worker safety for handling sharps during bone marrow procedures and

improving intradepartmental communications and timeliness of light duty and alternate work assignment placements.

Discussion
Group discussion focused on the following issues:

Communication with Clinical Center Staff
- Dr. Forese asked whether the Clinical Center has established a zero-tolerance policy, because it is best not to assume that everyone understands the urgency of the need to prevent workplace injuries and illnesses. Dr. Evans said that the Clinical Center has not established such a policy. She shared a story of a histology technician who reported that staff do not use gloves that are available to prevent sharps injuries. Leadership should communicate a zero-tolerance policy.

Additional Activities to Prevent Workplace Injuries
- Dr. Shannon emphasized the need to develop a detailed list of targeted initiatives to prevent musculoskeletal injuries that includes who will do what and by when. Monitoring trends over time will show how the institution is responding and improving.

Additional Occupational Safety Issues at the Clinical Center
- Ms. Bowie commented that some of the Clinical Center's wheelchairs are in poor condition and need to be repaired or replaced. Dr. Evans said that the bioengineering group, which manages wheelchair repairs, should establish a more stringent process to monitor wheelchair condition.
- Ms. Brinkley enquired about plans related to workplace violence. Dr. Evans explained that she tells every new employee that the Clinical Center has zero tolerance for violence. Employees are informed that police can be summoned without penalty, and a wealth of information is available on the center's emergency management site. Alfred Johnson, Ph.D., Acting Deputy Director for Management at NIH, added that there are police officers inside the Clinical Center at all times. In addition, the NIH Civil Program addresses the prevention of violence in the NIH workplace, and the employee assistance program offers a safe place to discuss concerns. The NIH police track potentially violent interactions, which are rare.
  - Dr. Forese asked about de-escalation training for staff. Dr. Evans replied that staff training does cover steps for de-escalation of violent patients. Dr. Pronovost suggested that the Clinical Center develop a centralized mechanism to monitor workplace violence.
  - Ms. Bowie noted that she has been coming to the Clinical Center regularly for 10 years, and she feels very secure at the center. Dr. Evans reported that quarterly police reports occasionally include one or two simple assaults involving altercations. Incidents involving patients are handled internally with the care team, but the police are called in if necessary.

Follow-Up Items

- Dr. Evans will ask the Bioengineering Group to monitor the condition of the Clinical Center's wheelchairs.
- Dr. Tabak will report to the CCRHB on any information about workplace injuries and illnesses at NIH that do not involve a visit to the Occupational Medical Service.

- The CCRHB requested updates on efforts to develop a zero-tolerance policy for employee harms at the Clinical Center and NIH.

Information Technology (IT) Infrastructure and Security
Andrea Norris, M.B.A., Director, Center for Information Technology; Chief Information Officer, NIH

Risk management requires a balance between risks to patient confidentiality, privacy, integrity, and security with the values that are integral to the NIH mission, including an open environment for research, collaboration, and clinical care. Maintaining this balance can be challenging.

The top priority for protection at NIH and the Clinical Center are its patients, employees, visitors, and research animals. Other protection targets are personally identifiable or personal health information, research data integrity, financial stewardship, and administration/operations.

NIH follows guidelines and policies from the National Institute of Standards and Technology, and the Department of Homeland Security scans NIH's public-facing systems weekly. NIH network traffic goes through a trusted internet connection that uses high-end equipment to monitor threats or trends. NIH also works closely with law enforcement and intelligence entities as appropriate.

NIH scans its large distributed network, which covers more than 130 buildings, for vulnerabilities, such as software that needs patching, to prevent intrusions. NIH does independent penetration testing several times a year, and all staff must take security awareness training every year. NIH has started controlled phishing exercises: if an employee clicks on one of these messages, he or she is taken to a description of the signs of a phishing scam. About 95% of the 14 million emails that come to NIH every day are blocked because they contain malware.

In addition to its electronic health record system, the Clinical Research Information System, and the Biomedical Translational Research Information System for clinical research data and analytics, the Clinical Center has more than 70 commercial and custom applications that support a wide range of functions and activities. In addition, the Clinical Center has 5,000 laptops, desktops, and mobile devices and 900 clinical workstations. Many different approaches and technologies are required to ensure that this environment is protected and secure.

Ms. Norris and colleagues have spent a great deal of time and effort in integrating security into every component of the Clinical Center's IT management and governance processes. For example, the Clinical Center's medical records do not include financial information or Social Security numbers, the Clinical Center also has strong role-based access and controls, and the Clinical Center undergoes more independent audits than other ICs, including an independent Department of Health and Human Services audit of its clinical systems. The NIH security team is constantly working with the Clinical Center in areas where the team can provide support.

Security is very dynamic and requires sustained leadership, support, investments in people and technologies, threat assessments, and adjustments. Processes are in place to monitor systems connecting to the NIH network at all times, and NIH can rapidly address known risks, such as critical vulnerabilities in commercial and custom applications, aging platforms and infrastructure, and penetrations. The agency also uses advanced security technologies for prevention and protection and developing new approaches to meet the demands for secure high-availability, high-quality IT services.

Discussion
Group discussion focused on the following issues:

Cybersecurity Risks
- Dr. Tuckson asked whether NIH has ever been hacked by a foreign government. Ms. Norris replied that the NIH networks and systems are routinely scanned for opportunities by nation states and entities all over world.
- Dr. Pronovost pointed out that medical devices and laptops that store personal health information are major risks to cybersecurity. Ms. Norris explained that one NIH goal is to allow employees to be as mobile as possible, as securely as possible. All laptops and mobile devices must be encrypted. The FDA and the Office of the National Coordinator for Health IT have some regulatory and oversight responsibilities in this area, and NIH works closely with its vendors to ensure the security of their devices.

Wireless Medical Device Technologies
- Dr. Tuckson enquired about strategies to facilitate the adoption of wireless technologies and ensure smooth transitions between the Clinical Center and other health-care organizations. Ms. Norris explained that NIH leaders support and are investing in wireless and networking technologies, and NIH can transfer patient data when needed.Brig. Gen. Burks noted that every medical device is now an information device, and manufacturers are sometimes less interested in information assurance issues than purchasers are. Mr. Norris explained that NIH requires certain controls and certifications through its acquisition process. However, technology changes constantly and some features are recognized as vulnerabilities only later, or a problem arises only when a device is connected to a particular system. The federal government is drawing industry's attention to this problem, which requires financial incentives to produce changes.

Clinical Trial Participation Facilitation
- Dr. Gallin reported that a recent inspector general review resulted in the elimination of a tool on the Clinical Center website that facilitated patient searches for relevant clinical trials. Ms. Norris said that her office is trying to develop a similar tool that is secure.

Interagency Partnerships
- Dr. Shannon asked about partnerships between NIH and other federal agencies to develop best-in-class approaches. Ms. Norris emphasized that she is very proud of the hard work done at NIH in a "rough" landscape. Cybersecurity requires continuous attention and investment, and today's sweet spot of controls and balances will be irrelevant tomorrow.

Follow-Up Items
- The CCRHB requested annual updates on cybersecurity.

Improving the Clinical Center's Census
Clinical Center Census and Reasons for Changes
John Gallin, M.D., NIH Associate Director for Clinical Research and Chief Scientific Officer, Clinical Center

Dr. Gallin presented average daily census data for the Clinical Center in FYs 2013–2017 (to date). Between FY 2016 and the first few months of FY 2017, the rates for inpatient admissions, outpatient visits, and average daily census declined, although average lengths of stay increased.

The number of inpatient visits for the National Cancer Institute (NCI), National Institute of Mental Health, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and the National Human Genome Research Institute also dropped between FY 2015 and FY 2016.

Some of this decline resulted from laboratory closures, but a major cause was the replacement of departing PIs with newer and less experienced PIs. It takes time for new hires to establish their research programs, and the Clinical Center lost approximately 6,000 patient days between FY 2012 and FY 2016 because of this shift. The losses for outpatient visits were similar.

Report from the Clinical Center Governing Board Working Group on Clinical Center Utilization
Steve Katz, M.D., Ph.D., Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases

Dr. Katz explained that Dr. Collins had charged a small group of internal experts to identify approaches to increase the patient census. Dr. Katz chairs this group, which developed consensus recommendations to address the most pressing issues and promising longer-term approaches for enhancing the inpatient census. The recommendations are also designed to strengthen the Clinical Center's role as a local, regional, and national research resource.

Recommendations to be implemented immediately are as follows:

- Use all necessary resources to accelerate ongoing enhancements to the Department of Transfusion Medicine
- Increase time available for use of the operating room
- Revisit the decision to shift costs to ICs for off-label drugs used in clinical protocols
- Provide assistant clinical investigators and their equivalents with dedicated, robust, clinical support
- Evaluate clinical research efforts by ICs that have intramural clinical research programs in the IC Directors' annual performance plans
- Issue a request for information to identify research areas where the need for inpatient research beds exceeds availability in the extramural community

Near-term recommendations (to be implemented in 3–6 months) are as follows:

- Charge all IC directors to identify two or three specific actions that will bolster the census in line with scientific priorities for clinical research
- Enable extramural institutions to bring inpatient studies into the Clinical Center
- Develop a more effective corporate process to ensure that budget decisions align with IC scientific priorities in determining capital investments and staffing priorities

Recommendations for recruitment and retention to be completed in 3–12 months are as follows:

- Develop a corporate personnel process to recruit individuals at all career development stages whose scientific goals require use of the Clinical Center's inpatient facilities
- Give highest priority to addressing critical research questions that can be most effectively and efficiently answered by interventions or procedures requiring hospitalization

Finally, the working group offered one longer-term recommendation:

- Accelerate the development of formal partnerships with local research centers, including Clinical and Translational Science Awards (CTSAs)

Discussion
Group discussion focused on the following issues:

Declining Census Concerns
- Dr. Tuckson asked why the declining census is a concern. Dr. Katz explained that this great resource is not used sufficiently. NIH needs new clinical investigators who will fully utilize the clinical research program, including inpatient and outpatient facilities.
- Dr. Collins added that the issue is not that NIH simply wants to fill more hospital beds, but to encourage the use of the most powerful facility in the world for doing clinical research, at a time when the needs of clinical research are compelling. NIH is doing fewer first-in-human trials, not because of a lack of scientific needs or great ideas, but because of a lack of clinical investigator staff who are prepared to implement these programs at scale. Many investigators who have left NIH are very experienced and were running large programs, and those who arrive need time to build their research programs. NIH trains great clinical investigators who institutions want to hire for higher salaries than NIH can offer. Dr. Tuckson suggested that when Drs. Gallin and Katz give this presentation in the future, they explain the reasons for the concerns about the census.

Clinical Research
- Dr. Shannon asked whether enrollment in the clinical research protocols of other research centers is also declining and whether the experience at the Clinical Center reflects a larger trend. Dr. Gallin reported that the use of outpatient facilities is increasing, but these facilities are used for fewer first-in-human studies and studies of rare diseases than inpatient facilities are.

Potential Reasons for the Census Decline
- Dr. Shannon said that restoration of the cell processing center is likely to reverse the loss of inpatients caused by its closure. Dr. Gallin said that half the loss of inpatients may be due to the facility's closure, and the difficulty of obtaining products formerly made by the Pharmaceutical Development Section (PDS) is also part of the problem. He suggested that NIH encourage other research centers to take advantage of the resources and expertise at NIH instead of building their own facilities. NIH could also encourage centers with patients who have a rare mutation to have their disease phenotyped as part of a study.
- Dr. Collins agreed with Dr. Shannon's suggestions. NIH is ramping up the All of Us research program, which will identify people with genotypes whose phenotypes are not understood. NIH will want to determine these people's phenotypes, and the Clinical Center could offer this service.Ms. Bowie pointed out that before the Affordable Care Act, many patients came to the Clinical Center because could not obtain insurance due to preexisting conditions.

Marketing Opportunities for the Clinical Center
- Brig. Gen. Burks wondered whether patients who used to go to the Clinical Center are going elsewhere and whether the market has emerging competitors, encouraging NIH to view the issue from the marketplace perspective. He also asked about the value proposition for using the Clinical Center, which is presumably based on its unique

capabilities. Dr. Gallin noted that the Clinical Center can offer services at a lower cost than private hospitals, because it only needs to recover the cost of bringing patients in.

- o Dr. Collins pointed out that NIH funds a network of 61 CTSAs that conduct clinical research and provide research training. In a sense, NIH is funding some of its own competitors. However, most CTSAs do not have the range of capabilities of the Clinical Center. The Clinical Center needs to find opportunities to do research that cannot be done elsewhere and should focus on recruiting new talent that can best utilize the unique resources that the Clinical Center provides.
- Dr. Tuckson suggested combining focus groups findings with a marketing campaign explaining the reasons to come to the Clinical Center. These reasons might include access to unique services and technologies, convenience, and lower cost.

Physician Recruitment/Increasing Engagement with Outside Physicians
- Dr. Katz reported that NIH is now offering joint appointments with local institutions. Brig. Gen. Burks recommended that NIH develop a human capital or talent management plan. Ms. Bowie asked whether NIH has clinical affiliations in addition to joint appointments. In many cases, outside clinicians want to continue to treat their patients after those patients visit the Clinical Center. Dr. Tabak explained that NIH clinicians may practice at other institutions, but this is considered an outside activity that must be separated from their official duties. Dr. Collins wondered whether NIH is taking full advantage of the status a practitioner at a local medical center might gain from an affiliation with the Clinical Center (e.g., invitations to grand rounds or other research-focused programs). Such affiliations might foster clinician support for research, and they might be more willing to consider enrolling patients in clinical protocols.
- Dr. Katz reported that his IC has consultant appointments for 35 local dermatologists, and all residents in dermatology in the city come to weekly grand rounds. Dr. Gallin added Clinical Center's grand rounds are always open to anyone who wants to attend, but potential participants say that the security is a barrier.
- Dr. Shannon commented that a new target of opportunity consists of the new clinical networks of physicians, primarily specialists, who might value an affiliation with NIH. In addition, the VA and Department of Defense offer exceptional pay to some practitioners in certain specialties. If NIH is struggling to retain senior investigators, offering this special status with its additional compensation might be helpful. Dr. Gallin said that NIH also has this system, Title 58, but does not have the same cap as the VA and Department of Defense. Parity with the other agencies would allow NIH to offer this incentive.

Follow-Up Items
- The Clinical Center census is of great interest to the CCRHB, which would welcome the opportunity to provide feedback.

Facilities Update: NIH Sterile and Non-Sterile Processing Facilities
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

The Intravenous Admixture Unit (IVAU), which supplies sterile pharmaceuticals, has had several compromises and is operating under a moderate level of control and heighted facility inspections. An interim IVAU will soon be ready for occupation, and NIH will replace the current IVAU with a new permanent IVAU by 2019. The interim IVAU will then be used for additional cell processing.

The Department of Transfusion Medicine, which supplies infusible materials for cell-based therapies, is operating under minimum physical control with robust administrative controls. Heating, ventilation, and air conditioning ductwork remediation and architectural finish repairs are expected to be complete in late January. All existing activities will eventually be moved to a new facility.

The positron emission tomography (PET) facilities produce sterile PET radiopharmaceuticals for human scanning studies. The B3 hot cell facility is still being monitored, but most physical concerns have been resolved, as is the case for the first-floor PET radiopharmacy facility. The co-located National Institute of Mental Health facility is consolidating its manufacturing activities with those of the Clinical Center's PET department.

The Nuclear Medicine Department Radiopharmacy has not manufactured any products, and it provides only commercially available products. Construction to enable sterile manufacturing is expected to be completed in mid-2017.

Additional cell processing is done in the NCI Surgery Branch's Cell Processing Laboratory, reopened in September 2016 after construction and renovations. NIH plans to move this laboratory into an unused facility, Building 53, on the NIH campus. The facility should be operational by May 2018. Because this new facility will still not provide the needed capacity, NIH is investing in two trailers with prefabricated GMP facilities.

The NCI Biopharmaceutical Development Program is in good shape. Although it needed some remediation, its production is continuing. The Leidos Radiopharmacy facility is operating at a high level of control, with minimal remediation required.

The National Institute of Allergy and Infectious Diseases vaccine stock manufacturing has undergone some changes in its administrative controls to allow continued operation until renovations are complete in March. The Malaria Vaccine Laboratory was considered for malaria vaccine production, but this work may be performed off campus.

The PDS has been closed since 2015, when all injectables it prepared were supposed to be quarantined and/or destroyed. An employee later discovered that some injectables that were not prepared for sterile use had been kept. A sweep was conducted, and all remaining non-sterile products prepared in the PDS are now quarantined. NIH is now identifying other sources from which to purchase the needed products and making products on an ad hoc basis.

Closing Statement and Adjournment of Open Session
Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian, and Chair, CCRHB

A motion to approve the minutes of the CCRHB meeting on October 21, 2016, carried. The next face-to-face CCRHB meeting is scheduled for April 28, 2017. Dr. Forese and Dr. Collins thanked the board members for their thoughtful input. Dr. Forese adjourned the open session at 3:15 p.m.

Closed Session
This section of the meeting was closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 USC. The materials and discussion could

disclose information on the internal personnel practices or rules of the National Institutes of Health, as well as personal information associated with the individuals under consideration for leadership positions, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Adjournment of Closed Session
Dr. Forese adjourned the closed session at 4:15 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

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Lawrence A. Tabak, D.D.S., Ph.D.
Executive Director, NIH Clinical Center Research Hospital Board
Principal Deputy Director, NIH

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Francis S. Collins, M.D., Ph.D.
Ex Officio Member, NIH Clinical Center Research Hospital Board
Director, NIH

Abbreviations and Acronyms

AE	adverse event
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CLABSI	central line–associated bloodstream infection
CMS	Centers for Medicare & Medicaid Services
CTSA	Clinical and Translational Science Award
FDA	Food and Drug Administration
FY	fiscal year
GMP	good manufacturing practice
IC	Institute and Center
IRB	institutional review board
IT	information technology
IVAU	Intravenous Admixture Unit
NCI	National Cancer Institute
NIH	National Institutes of Health
PDS	Pharmaceutical Development Section
PET	positron emission tomography
PI	principal investigator
SAE	serious adverse event
UP	unexpected problem
VA	Department of Veterans Affairs