

# Clinical Center Research Hospital Board

## Inaugural Meeting

July 15, 2016

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    NewYork-Presbyterian, and Chair, CCRHB

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## **Participants**

### ***Clinical Center Research Hospital Board***

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

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

Francis S. Collins, M.D., Ph.D., Director, NIH, Ex-Officio Member, CCRHB

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

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

Carolyn Clancy, M.D., Deputy Under Secretary for Health for Organizational Excellence, Veterans Health Administration

Jeanette Erickson, RN, DNP, Senior Vice President for Patient Care Services, Chief Nurse, Massachusetts General Hospital

Paul O'Neill, M.P.A., Non-Executive Chairman, Value Capture LLC

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

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

## **Executive Summary**

The first meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on July 15, 2016, on the NIH main campus. The meeting was open to the public and was webcast live. Francis Collins, M.D., Ph.D., Director, NIH, welcomed the CCRHB members and showcased key statistics pertaining to the Clinical Center and described several of its special features. He also reviewed the sentinel event that led to the Red Team's recommendations, one of which was the formation of the CCRHB. Finally, he offered some feedback from Clinical Center staff on the Red Team's report.

A series of presentations by NIH staff provided insights into the reactions of NIH leaders to the Red Team report. The first presenter was John Gallin, M.D., Director, NIH Clinical Center, who provided an overview of the Clinical Center, the world's largest research hospital. The second presentation was by Laura Lee, RN, M.S., Director, Office of Patient Safety and Clinical Quality, and Special Assistant to the Deputy Director for Clinical Care, who presented data on patient safety metrics that have been routinely collected at NIH for some time. She also informed the CCRHB about how information on metrics is disseminated throughout NIH. Henry Masur, M.D., Critical Care Medicine Department, spoke on behalf of the clinical department heads on the need for changes in Clinical Center governance and funding. He observed that the existing system of governance was set up in the 1950s; the perspectives of all who are involved in clinical research and the delivery of patient care have changed greatly since that time. Avindra Nath, M.D., Clinical Director, National Institute of Neurological Disorders and Stroke, and Chair,

Medical Executive Committee, presented a report on behalf of the Medical Executive Committee. He highlighted some of the unique challenges involved in governing the Clinical Center and also offered some suggestions to be considered by the CCRHB.

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, and Executive Director, CCRHB, presented the organization structure as it exists now and proposed a revised structure that includes several new positions, including the chief executive officer (CEO), as recommended by the Red Team.

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian, and Chair, NIH CCRHB, reviewed the responsibilities ensconced in the new CEO position and initiated a discussion about key characteristics that the search committee should look for in candidates.

## **Meeting Summary Friday, July 15, 2016**

### **Welcome and National Institutes of Health (NIH) Director's Overview**

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

The first meeting of the NIH Clinical Center Research Hospital Board (CCRHB) took place on July 15, 2016, on the NIH main campus. The meeting was open to the public and was webcast live.

Dr. Collins welcomed the board members, noting that three members (Ruth Brinkley, M.S.N./Adm.; Brig. Gen. James Burks; and Peter Pronovost, M.D., Ph.D.) were unable to attend. The board members introduced themselves, and Dr. Collins acknowledged the contributions they had made during teleconferences preceding this inaugural meeting. In addition, he thanked the staff of the NIH Office of the Director for their work planning this event.

#### ***The Clinical Center***

Dr. Collins showcased some important features of the Clinical Center and the research it supports:

- Staff of 1,900 employees
- Budget of \$420 million for fiscal year (FY) 2016
- Largest hospital in the world devoted exclusively to clinical research
- More than 1,600 studies in progress
- Approximately 500,000 volunteers have participated in research since the opening of the Clinical Center
- 10,000 new participants in clinical studies each year

Among the many significant biomedical developments made possible through research conducted at the Clinical Center are the following:

- Chemotherapy treatment of cancers
- Treatment of heart attacks with nitroglycerin
- Gene therapy trials
- Immunotherapy for cancers
- Vaccines against *Haemophilus influenzae* type b and human papillomavirus
- Blood tests for HIV and hepatitis

Dr. Collins pointed out that these advances have affected the lives of millions of people; in fact, the Clinical Center was honored with the Lasker-Bloomberg Public Service Award a few years ago.

The Clinical Center has a proud history of tackling public health challenges, including Ebola virus. Two Ebola patients were treated in the Clinical Center's high-level containment facilities,

discharged free of the virus, and returned to their communities. The National Institute of Allergy and Infectious Diseases is now conducting trials of two promising vaccines against Ebola virus. In addition, the Zika virus epidemic has prompted NIH investigators to launch the first trials of a DNA vaccine against the virus.

### **Red Team Report**

In May 2015, an unannounced inspection by the U.S. Food and Drug Administration (FDA) uncovered problems with facilities, equipment, procedures, and training in the Pharmaceutical Development Section (PDS) due to multiple deficiencies in Good Manufacturing Practices (GMPs). Dr. Collins underscored that no patients were harmed as a result of the lapses. The problems were investigated by a high-level NIH task force, which issued a [report](#) concluding that the deficiencies could indicate systemic problems extending beyond the PDS. To assess the situation and identify actions, Dr. Collins assembled the [Clinical Center Working Group of the Advisory Council to the Director \(ACD\)](#), which included outside experts, and was christened the Red Team.

The Red Team's report was approved by the ACD and accepted by Dr. Collins. The report offered recommendations in three major areas:

1. NIH needs to fortify a culture and practice of safety and quality.
2. NIH must strengthen leadership for clinical care quality, oversight, and compliance.
3. NIH is obligated to address sterile processing of all injectables used in the Intramural Research Program, as well as the specifics of the sentinel event.

A key recommendation of the Red Team was the formation of an external hospital board (i.e., the CCRHB) to be charged with making recommendations to the NIH Director on the organization and management of the Clinical Center. The board will receive regular reports on safety metrics and other topics.

The Red Team also recommended creating the new position of chief executive officer (CEO) to be responsible for managing the hospital and working closely with the CCRHB. The job announcement was released the day of the meeting (<https://jobs.nih.gov/vacancies/executive.htm>). Another leadership position will coordinate with the NIH Institutes and Centers (ICs) on all research activities in the Clinical Center and develop a plan for allocating Clinical Center resources among the ICs.

Additionally, the Red Team recommended establishing a Clinical Practice Committee (CPC) to develop policies, drawing upon expertise across many specialties, to improve the Clinical Center.

Another step is the establishment of the Office of Research Support and Compliance. The office's functions previously resided within the ICs but are now centralized. Andrew Griffith, M.D., Ph.D., will serve in an approval capacity, and Valerie Bonham, who has expertise in human subjects protections, will serve as the Deputy Director. A permanent Director is currently being recruiting. To address issues related to sterile processing, Bruce Burnett, Ph.D., Director of

Regulatory Affairs within the Duke Translational Medicine Institute, will join NIH on a temporary basis.

All NIH facilities that produce sterile injectables have been inspected. Efforts are under way to remediate, consolidate, or close facilities in order to meet standards. Some facilities will need to be rebuilt to meet GMP standards.

Other changes include the following:

- Performance plans for clinical staff will include elements related to patient safety.
- An [anonymous, toll-free hotline](#) has been set up to allow anyone to report patient safety events in the Clinical Center. All calls will be reviewed for follow-up and action.
- [Safety metrics](#) are now displayed on the home page of the Clinical Center. These data have been collected for years, but they are now more readily accessible.

### ***Feedback from the Clinical Center Staff***

According to Dr. Collins, certain conclusions of the Red Team have created heartache and distress among the people who work in the Clinical Center. The large majority of doctors, nurses, and other staff are dedicated and hardworking; many turned down more lucrative positions in order to further the research agenda of NIH and help patients. Grateful patients communicate with NIH about the excellent care they received in the Clinical Center, which many patients consider a “house of hope.” The perception that staff might be more interested in publishing papers than caring for patients has caused pain.

Dr. Collins spoke of the need to listen to Clinical Center staff about their reactions and concerns. Dr. Collins and Lawrence Tabak, D.D.S., Ph.D., have met with many staff about the Red Team’s findings. To gather additional feedback, Steven Holland, M.D., Dr. Griffith, and others organized town hall meetings with Clinical Center staff. Focus groups will collect more information. NIH clinical staff and NIH leaders want to work as partners with the CCRHB.

The topic of change at the Clinical Center is on the radar of the U.S. Congress. Appropriations language for FY 2017 acknowledges the issues under discussion. Fragmented accountability and governance was mentioned by the Senate, which also noted that adopting a centralized structure made sense. The House of Representatives was more prescriptive in its recommendations to replace the leadership of the Clinical Center and to use intramural resources for implementing changes rather than shifting funds from the extramural budget. Over the years, Congress has been very supportive of NIH and the Clinical Center, but there is clear interest in the outcome of activities aimed at improving patient safety and fostering an environment of continuous improvement.

Dr. Collins said he was excited about the variety and level of expertise represented on the CCRHB. The clinical staff have been working diligently to implement the Red Team’s recommendations. Change management is always challenging, but the goal is to strengthen and enhance the Clinical Center’s already stellar reputation.

## ***Discussion***

Laura Forese, M.D., M.P.H., noted that Mr. Norm Augustine, chair of the Red Team, said that any member of the Red Team would go to the Clinical Center without any hesitation if the need arose. Dr. Forese expressed the hope that this message could be shared more broadly.

The sentinel event presented an opportunity to improve. The Red Team members are from institutions that have backgrounds in and experience with continuous improvement. Every hospital in the world wants to be better, and so does the Clinical Center. The Red Team outlined a framework to advance all NIH priorities, including patient safety. That message, unfortunately, has not been picked up by the press. Unfortunately, much of what was reported in the press was taken out of context or was exaggerated.

Other members of the CCRHB raised various points:

- The briefing materials provided to the board were very thorough.
- Safety of workers needs to be considered. Medical care is the most dangerous profession by a wide margin.
- The Clinical Center is a place with talented, well-educated people who are demonstrating to the world what is possible even when patients are seriously ill with diseases that are not fully understood.
- The Clinical Center is unique in that safety has two components: research safety and clinical care safety.
- The staff of the Clinical Center should be engaged in telling the story of cures being developed and diagnoses being made. The effort to improve the safety of research participants will be a journey in itself and will be a story worth telling.
- Regarding concerns about low morale among Clinical Center employees, perhaps a place should be set up where people can talk about their frustration and grief to help them resolve their feelings.
- The majority of health care systems in the country are going through similar exercises of introspection. The complexity of human disease is increasing substantially. The systems and processes that once served medicine well will need to be upgraded. However, at the Clinical Center the situation has an additional layer of complexity: making discoveries focused on bettering the human condition.

Dr. Collins asked about the members' experiences with change management within their home institutions. What lessons learned during those processes led to staff empowerment?

- It is necessary to emphasize the importance of daily, real-time discoveries from staff about opportunities for improvement. It is important to learn about what can be improved upon today compared with what was done yesterday. The staff doing the hands-on work are the way forward. Think about tools that people can use every day in self-discovery to get information, rather than having people sit and discuss around a table.
- Safe systems cannot exist without the full involvement of the staff.
- The role of leadership is to provide what staff need to execute their jobs in the real world.

- Communication is the key to responding to a sentinel event. Communication can help people understand how the organization got to a point where someone made a serious error. Publishing about what happened and how the organization responded is important.
- The CCRHB is here to help NIH navigate the process and learn from the experience. Together, the board and NIH can make things better and apply the lessons learned to improve health care around the world.
- Top leadership needs to establish and articulate aspirational goals. An example is Allegheny General Hospital’s goal of having no central line infections. The hospital’s nurses had all been trained in different schools, and each used a different process; getting to “perfect” meant having the nurses agree to a standard process and providing properly fitting, high-quality safety equipment. Another benefit was an increase in employee satisfaction and pride.
- What is happening at NIH is no different from what is happening all over the United States. Every health care institution has to ask itself how it can safely deliver exemplary care in an increasingly complex environment. Finger-pointing and pushing people into defensive postures only makes them resistant to change.
- NIH is all about discovery. Discover, apply, and export best practices: That is the core of this effort. The CCRHB should support and encourage the people who are striving to improve patients’ lives.

Dr. Forese summed up the discussion, saying that as NIH strives toward perfection—zero preventable events and best possible outcomes for patients—NIH leaders need to think about the conditions that led to the sentinel event and how it can support front-line staff to help them succeed. The CCRHB has a role in facilitating these goals and holding people accountable. To ensure that everyone understands that he or she has a role in these efforts, a great deal of discussion and listening will be necessary. The CCRHB is committed to hearing from NIH leaders and Clinical Center staff.

## **Clinical Center Leadership Feedback**

### ***Overview of the Clinical Center***

John I. Gallin, M.D., NIH Clinical Director

Dr. Gallin said that the most rewarding part of his career as the director of the Clinical Center for 22 years has been the privilege of caring for some of the sickest patients in the world and having the thrill of discovering new treatments to help them. Everyone here has striven to make the Clinical Center a safe environment, but everyone also recognizes the potential to improve.

Dr. Gallin described the Clinical Center as the largest hospital in the world wholly dedicated to clinical research. Key mission elements include clinical research, patient care, and training and education of researchers. Every patient is a partner on a research protocol. The Clinical Center enables 17 NIH Institutes’ clinical research, including studies of disease pathophysiology, first-in-human trials of new therapeutics, and natural history studies of nearly 500 rare diseases.

The Clinical Center's budget is allocated at the beginning of each fiscal year. No revenue stream is generated by billing for care, nor does the Clinical Center benefit from direct philanthropy. The Clinical Center is not a full-service hospital; it has no emergency or obstetrical department. The hospital is enveloped by research labs.

Dr. Gallin highlighted a few major accomplishments achieved through research conducted at the Clinical Center; the list reflects the dedication of each Institute to research. He also provided a snapshot of the hospital, noting that more than 500,000 patients have participated in Clinical Center research since the facility opened in 1953. The average length of stay is 8.5 days, and the average daily census is 131 patients. In 2015, the Clinical Center logged nearly 48,000 inpatient days; 100,000 outpatient visits; and 11,000 new patients. The current budget is \$424 million. The hospital has 200 beds, 13 ambulatory clinics, 93 day-hospital stations, and 11 operating rooms, supported by a staff of 2,657 Clinical Center employees and 6,764 Institute employees, among whom are more than 1,300 credentialed physicians.

Of the more than 1,600 active protocols, 49 percent are interventional/clinical trials, 45 percent are natural history studies, 4 percent are screening protocols, and 2 percent are training protocols.

Dr. Gallin pointed out that no other facility can conduct studies for which the length of stay often exceeds a month. He listed the Clinical Center's 14 inpatient units, called out the behavioral health units, and mentioned the Special Clinical Studies Unit for patients with rare, highly contagious diseases, such as Ebola, and for conducting certain challenge studies for vaccine development.

The specialized facilities of the Clinical Center provide strong phenotyping capabilities. The list of resources includes biomechanics laboratories, metabolic chambers, cell processing facilities, positron emission tomography equipment, and cyclotrons to produce nuclear medicine products.

The Clinical Center is supported by a state-of-the-art, fully integrated electronic health record system. A patient portal is available, and a referring-physician portal is being set up. The Biomedical Translational Research Information System merges clinical and research data, provides reporting and analytical capabilities, and facilitates reporting to [clinicaltrials.gov](http://clinicaltrials.gov).

Training is a key component of the NIH mission. The Clinical Center is a sponsoring institution for 17 programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) in addition to more than 30 other non-ACGME programs. The Clinical Center staff also receive training on regulatory topics, hospital/clinical quality, and patient safety issues. NIH training reaches 40,000 students in 26 countries around the world.

Dr. Gallin summarized seven significant reviews of the Clinical Center done in the past. Among the recurring themes were patient safety, funding of the Clinical Center, governance structure, staff recruitment and retention, and the sharing of Clinical Center resources with extramural investigators.

Dr. Gallin pointed out that adjusting the Clinical Center budget for inflation reveals a gap totaling \$46 million dollars over 12 years. Last year's budget had to be increased because of heightened drug costs. Implementing the remediation strategies recommended by the Red Team could cost as much as \$50 million. The result of persistent budget shortfalls is the underfunding of capital equipment and deferral of needed facility upgrades.

Dr. Gallin presented the Clinical Center's governance structure as of March 2016. He also listed the many groups that review the Clinical Center regularly.

### ***Review of Current Safety Metrics***

Laura Lee, RN, M.S., Director, Office of Patient Safety and Clinical Quality, and Special Assistant to the Deputy Director for Clinical Care

Ms. Lee presented the framework for patient safety and quality efforts at the NIH Clinical Center designed to ensure that the Clinical Center supports an environment conducive to continuous improvement of quality.

Risks are associated with hospitalization. Medical errors, according to a study done by Johns Hopkins University, are the third leading cause of death in the United States. At the Clinical Center, there are the added risks of participating in clinical research. Phase 1 and 2 trials always entail risk, even though many preclinical studies are performed. Complexity and risk come together at the intersection of patient care and clinical research.

NIH has a straightforward approach to patient safety and clinical quality. Risk assessment, surveillance processes, event analysis, and quality improvement and organizational learning are important elements of patient safety at the Clinical Center.

Although the Red Team reported that the NIH Clinical Center does not collect key hospital metrics on patient safety, that is not the case: Most metrics have been collected for a decade or longer. Ms. Lee offered an example of how NIH uses these data to reduce central line-associated bloodstream infections (CLABSIs). Surveillance detected an uptick in the number of infections per 1,000 catheter days that was temporally associated with the introduction of a new product. Investigation revealed several problems with central line use, including practice variation among staff and a lack of standard equipment to manage these devices. Standardization of practices and equipment, augmented with education and raising awareness for all Clinical Center staff, led to significant improvement. Similar efforts have maintained the Clinical Center's record on patient falls to a level well below the national average and decreased delays in initiating STAT antibiotic infusions in the intensive care unit.

Regarding metrics for patient safety and quality of care, Ms. Lee explained that many population-based metrics (e.g., incidence of stroke and heart failure) and surgery-specific metrics do not apply, because of the special populations the Clinical Center serves. Nevertheless, NIH is

always looking for better ways to measure performance. The clinical departments of the Clinical Center have active measurement programs. Nearly 200 metrics are used to monitor performance and drive improvement. A “critical few” metrics guide operations/management. Some NIH programs focus on measures related to clinical care.

Ms. Lee identified several opportunities for improvement:

- Revise the current patient safety and clinical quality plan of the Clinical Center, based on visits to other hospitals.
- Expand measurement activities, based on gap analysis of industry metrics.
- Use safety and quality activities related to the conduct of clinical research when developing IC-based metrics.
- Expand existing education/training programs on patient safety and quality improvement.
- Standardize processes for collection and reporting of metrics and for quality improvement throughout the organization.
- Increase investments to enhance existing Clinical Center programs on patient safety and clinical quality and establish IC-based programs that are aligned with those of the Clinical Center.

### ***Ensuring a Vibrant Future***

John Gallin, M.D., Director, NIH Clinical Center

Dr. Gallin stated that NIH leaders and staff can instill a stronger culture of safety and continuous quality improvement to make the Clinical Center the best biomedical research facility in the world. Doing so will involve aligning the responsibility and authority of Clinical Center leadership related to clinical care and facility oversight. The Clinical Center’s decentralized administration works well for a research organization, but not for a hospital. The director of the Clinical Center has no direct oversight for the facility. One entity is in charge of oversight for all NIH facilities.

The budget of the Clinical Center must be stabilized. The hospital needs an independent budget line, and funding must be adjusted to close the inflation deficit and permit facility upgrades. A new wing is needed to house departments that are aged or “stranded.” The operating rooms, for example, have not been improved for more than 30 years.

Personnel systems are antiquated. Salaries are too low to attract scarce medical specialists, and the arcane position classification has led to odd disparities in salaries.

### ***Discussion***

Dr. Collins observed that senior leaders in the Clinical Center were apparently unaware that patient safety metrics have been collected for some time; therefore, they were not able to inform the Red Team about the metrics. He asked about the pathways for sharing information about metrics with senior leaders to ensure that the information is used to direct patient safety and quality improvement.

Ms. Lee said that data on CLABSIs are collected and shared at meetings of the infection control group and are also shared at nursing forums at the leadership and unit levels. In addition, Tara Palmore, M.D., presents data on infection control metrics to the Clinical Quality Committee. CLABSI data (number of infections, not rates) are pushed down to the local level almost continuously. Ms. Lee acknowledged that there is room for improvement in terms of pushing out metrics to clinicians. The clinicians conduct excellent research, but they are not very involved in hospital-based committees. She asked about ways that other institutions disseminate information on metrics to the people “on the ground.”

Paul O’Neill, M.P.A., asked about an important metric: injuries to the employees who deliver care (e.g., Occupational Safety and Health Administration [OSHA] recordable injuries and illnesses, lost work days). Employee safety metrics are the best and most profound measures of habitual excellence in an institution. Workers need to be taught how to do their work safely, and leadership needs to invest in equipment (e.g., mechanical lifts) to prevent worker injuries. Repeat offenders should be identified and sent to work elsewhere. Mr. O’Neill suggested installing computer screensavers that present real-time safety data. Root-cause analyses should be performed within 24 hours for worker injuries and other events. Only then will there be real progress toward achieving zero safety problems. There is real potential in leveraging lessons from an incident so it is not repeated again.

Ms. Lee reported that NIH has an occupational medicine service that tracks incidents such as back injuries and needle sticks. For example, last year there was an uptick in the number of back injuries in the operating suite, and training was immediately put in place to correct the trend. An increase in back injuries in the morgue led the National Cancer Institute (NCI) to build a new morgue. Dr. Gallin added that widely adopted protocols for preventing and responding to needle sticks were first developed at NIH.

Jeanette Erickson, RN, DNP, asked about the barriers to improving safety. Ms. Lee said that a large catalog of training opportunities is available, but staff find it challenging to set aside time for training. Also, online training needs to be augmented with in-person training. Dr. Gallin said that some trainings are required for renewing credentials, but more could be done to support employees so they can participate in additional trainings.

Reed Tuckson, M.D., asked about the process for credentialing the 1,148 physicians who are not Clinical Center employees but are employees of other ICs. (Only 184 of the credentialed physicians working in the Clinical Center are actually employees of the Center.) He also inquired about the mechanism for deciding whether an event is a disease outcome or the result of intervention. Who has the power to intervene, and who decides what the IC physicians have authority to do? Dr. Gallin explained that the 1,148 IC physicians are not outsiders; they are seamlessly integrated with Clinical Center staff with whom they work, side by side, in patient care. The clinical directors are responsible for the immediate quality of care for each IC. Every year, the clinical directors review documentation to ensure that everyone’s clinical performance

meets requirements. The Medical Executive Committee (MEC) also conducts annual reviews to ensure that everyone is up to date. However, there is variability across the ICs in how they address their responsibilities. Regarding accountability, Dr. Gallin said that every IC is charged with convening morbidity and mortality conferences. The quality of these conferences does vary, however. In the surgery programs, this variability is of particular concern. Dr. Gallin said that he has appointed W. Marston Linehan, M.D. to implement central reviews of morbidity and mortality events. Also, efforts are underway to increase the number of grand rounds, morbidity and mortality conferences, and teaching/training conferences across the entire organization. If there is a near miss, then Ms. Lee conducts a root-cause analysis.

A board member asked whether variability in the ways ICs evaluate adverse events could affect clinical trial results. How do researchers know that the outcome of the experimental intervention was not affected by poor clinical care? Dr. Gallin acknowledged that this question is difficult to answer; however, data safety and monitoring boards (DSMBs) and institutional review boards (IRBs) have robust processes that evaluate events occurring in a clinical research protocol. Also, the Office of Human Research Protections reacts quickly.

Ms. Lee said that her organization has been collaborating with the IRBs over the past 5 or 6 years in collecting and reviewing protocol deviations and adverse events in an effort to identify systemic problems.

Carolyn Clancy, M.D., spoke of the need to empower people to report problems, by bolstering the sense of psychological safety in the organization. Quality leaders in academic systems are exploring whether surveys give insights into what might occur downstream—in essence, serving as an early warning system.

### ***Report from Clinical Center Department Chairs***

Henry Masur, M.D., Critical Care Medicine Department

Dr. Masur spoke on behalf of the clinical department heads on the need for changes in Clinical Center governance and funding. The governance system, which was set up in the 1950s, needs to be updated. The perspectives of everyone involved in clinical research and the delivery of patient care have changed greatly since that time.

Regarding the observations of the Red Team, Dr. Masur said that the Clinical Center is a research hospital that has attracted clinicians who are interested in research. The clinical department heads believe that the care provided at the Clinical Center is as good as or better than that given at any other major medical center. Putting research goals above patient care is not emblematic of the Clinical Center or the intramural program, although there may be some staff who are outliers.

Regarding the PDS closure and the report of the Red Team, Dr. Masur observed that the Institutes provide the Clinical Center with inadequate funding to deliver services they expect for

their research portfolios. He further noted that governance and decision-making would benefit from more input from staff who have recent clinical and hospital management experience.

All health care facilities deal with errors, near misses, and “never” events. NIH needs to take ownership of each such event, learn from it, and take action to reduce the likelihood it will recur. The Red Team insightfully recognized many organizational challenges in the Clinical Center, but Dr. Masur thought that the recommendations and subsequent actions did not dovetail with the current challenges.

The NIH Intramural Research Program has quality assurance and safety programs, and it undergoes regular reviews by the Joint Commission, the College of American Pathology, the American Association of Blood Banks, ACGME, and the Association for the Accreditation of Human Research Protection Programs. The Clinical Center performs well, according to the benchmarks of these organizations and many others.

All clinical center departments have appropriate quality assurance and safety programs that are adapted to the patient population. Challenges do exist, though. For example, the Clinical Center Office of Safety is understaffed and under-resourced, and the remediation of quality changes could be better were it not hampered by diffusion of authority, multiple standards, and variable decision-making abilities.

Dr. Masur presented a list of the NIH Clinical Center’s clinical department heads. The departments receive high marks from various accreditation groups, yet the heads are not included in decision-making for the hospital. The Red Team interviewed only one head of a clinical institute and none of the heads of the clinical departments and very few individuals who are active clinically. Also, the department heads were unclear how the Red Team came to the conclusions that were reached on the quality data that the hospital or the institutes collect. The Clinical Center is a successful institution of which the staff are proud and where programs that have impacts over many years can be developed. Examples include research on immunodeficiencies, HIV/AIDS, and renal cell carcinoma. The American taxpayer can take pride in the work accomplished in the Clinical Center.

Dr. Masur spoke about supervision of clinical staff in the Clinical Center. Employees of the Clinical Center answer to the Clinical Center Director, and the clinical department heads. IC staff report to the IC Director, the IC Scientific Director, the relevant branch and laboratory chief, and providers. Thus, the IC Clinical Directors in fact do not supervise the clinicians in their Institute other than the clinicians that might be in their particular branch or lab. The Clinical Center Director does not directly supervise IC staff.

The Clinical Center has very few hands-on care providers. Multiple ICs provide clinical services, based on historical agreements that are word of mouth, and not written. Dr. Masur pointed out that there is no single standard for quality oversight in the Clinical Center. Intramural quality of care is usually stellar; however, in unusual situations (e.g., physician performance, staff

conduct), Clinical Center leads might have to go to the Clinical Director of the relevant IC, who might or might not take the action that CC sees as appropriate. Remediation of issues related to patient safety and quality of care is a challenge because of the need for decision making that meets both Clinical Center and Institute standards. The standards of the Clinical Center do not necessarily align with the standards of the ICs. In addition, there is no clear and ultimate responsibility for remediating problems.

To improve the operations of the Clinical Center, three overarching topics need to be addressed: governance, budget, and facility control. When the hospital was established in the 1950s and 1960s, the expectations for Clinical Center leadership were very different: Leaders of the CC were expected to stabilize the budget and permit the Institutes to perform according to their own standards, without formal oversight by the Clinical Center. For this reason, budget control is seen as a matter of the Clinical Center achieving management efficiencies. The role of the ICs in controlling expenses is underemphasized.

Clinical Center governance is diffuse. Under-represented among oversight committees and decision-makers are physicians and nurses who have recent clinical expertise and successful managerial experience. The governance developed in an earlier era does not fit modern hospital management. The Clinical Center Director needs to have a more active supervisory role over all the health care providers in the facility. In addition, the Director should be a partner in a much more effective NIH-wide process to match IC clinical research goals with Clinical Center resources.

With regard to funding, Dr. Masur pointed out that the current budget system requires Institutes to fund Clinical Center expenses from their own intramural research budget. This leaves the Clinical Center to bear the burden of reducing costs without any control of what the providers are doing. In addition, current funding does not adequately support capital equipment purchases. The Clinical Center needs facility modernization and maintenance and to be able to recruit and retain quality staff. The hospital needs an independent budget that is not a derivative of IC intramural funds and is reflective of true medical costs (including inflation). The Institutes cannot expect uniform quality if the CC is underfunded.

Dr. Masur also remarked on the low morale among Clinical Center staff. Change is difficult and uncomfortable. The hope is that the CCRHB recognizes that the nation should be proud of the accomplishments of the Clinical Center and the Intramural Research Program. In closing, Dr. Masur highlighted several needed actions that the CCRHB could initiate:

- Fix the governance structure of the Clinical Center. The Clinical Center Director needs to have authority over clinical staff. Currently responsibility and authority are misaligned.
- Ensure that more decision-makers and advisors have recent clinical and hospital managerial experience.
- Fix the budget process by creating a rational system to match resources with clinical expectations.

- Fix authority over hospital facility. Allow Clinical Center leadership to manage the medical facility.
- Address the declining morale of Clinical Center staff.
- Initiate management reform based on an in-depth analysis of this complex organization and lessons learned from other academic centers. An effective solution will require more than several new committees.
- Encourage new leadership to champion modernization of governance and management, and to recognize the special strengths and advantages of a Federally funded intramural hospital.

***Report from Medical Executive Committee***

Avindra Nath, M.D., Clinical Director, National Institute of Neurological Disorders and Stroke, and Chair, Medical Executive Committee

The members of the MEC met several times to review the Red Team report. Dr. Nath remarked that the Clinical Center studies a large number of healthy volunteers who serve as normal controls. In addition, the Clinical Center supports many natural history studies that do not entail research interventions.

The organizational structure of the Clinical Center is not based on departments as most hospitals are. For example, medical and surgical subspecialists are spread across different ICs. The lack of an emergency department may mean a reduced chance for medical errors, but it also means that patients with emergency situations sometimes have to be transported elsewhere.

Clinical research is closely overseen by the scientific review committee, the Clinical Director of the IC(s) involved, the IRB, a DSMB and/or an independent medical examiner, and FDA (if the protocol is FDA-regulated research).

The MEC, composed of the various Clinical Directors of the NIH Intramural Research Program and other senior medical and administrative staff, advises the Clinical Center Director and develops policies governing standards of medical care in the Clinical Center. Meetings occur every 2 weeks and generally are open, with the exception of executive sessions. Several standing committees exist, each dealing with some aspect of patient care.

The IC Clinical Directors report to the hierarchy of their own Institutes and Centers. These directors review the IC's clinical protocols, oversee research coordination, evaluate quality of patient care, disseminate and implement improvements in quality and safety, evaluate resource utilization, take corrective actions, oversee educational activities for clinical privileges, and serve as voting members of the MEC.

Dr. Nath highlighted some important challenges from the Red Team report:

- The reporting structure and resources available to Clinical Directors are highly variable. Many Clinical Directors report to Scientific Directors, who are often basic scientists. The Red Team recommended that the Clinical Directors report to the IC Directors.
- The MEC has no control over performance, budget, or resources for clinical programs in the ICs.
- Per the Red Team, clinical competency is an issue. For example, surgeons rarely get opportunities to perform appendectomies.
- The MEC has no oversight of facilities.
- The MEC has no role in the recruitment of clinical faculty.
- The Clinical Center would benefit from having pediatric care. Currently, there is no pediatric intensive care unit (ICU) or neuro-ICU. Given the number of genetic diseases being studied at NIH, being able to care for children is seen as a critical need.
- The Red Team recommended formation of a CPC with six to eight members. Carrying out all the identified tasks would entail significant commitments by the members.

Dr. Nath proposed several ideas:

- Develop clear lines of authority and communication.
- Have Clinical Directors participate in decision-making for key hires.
- Give the Clinical Directors a role in organizing the Clinical Practice Committee and developing mechanisms of interactions with the MEC.
- Give the Clinical Directors budgetary authority within their ICs.
- Develop clinical practice groups for establishing practice parameters, teaching, and establishing a salary structure.

### *Discussion*

- Given the need for specialists to perform some low-volume interventions, why not employ hospitalists? Dr. Masur said that more thought should be given to how hospitalists could fit into certain services at the Clinical Center. NIH does have some full-time staff clinicians who serve to some extent as hospitalists. The ICU has some full-time clinicians who do research part-time. He also asked why someone would want to work at NIH for a low salary if there is no opportunity for research.
- What is the incentive for the proceduralist who is called on to do a procedure? In some environments, physicians earn more money if they perform more procedures. Dr. Masur said that it takes a special kind of person to work at NIH, someone who is able to balance research and clinical care. NIH physicians like to maintain their clinical expertise, but they also want to do research. Dr. Nath clarified that there is no financial incentive for clinicians to perform procedures.
- Dr. Forese remarked that the foregoing presentations brought to light certain things that make this institution special, but there are similarities with other institutions. For example, at an academic medical center, the hospital does not employ the physicians who do the majority of the work, but the physicians are still required to adhere to the institution's standards.

- With no emergency department, how are acute problems handled in the Clinical Center? The response was that the ICU can provide emergent care if the research participant is able to get to the Clinical Center. The research team knows a great deal about the participant's history and can help him or her through a crisis. Nevertheless, if someone is having a stroke, for example, he or she should go to another health facility that is better equipped to handle the situation.
- How do you maintain quality of staff in a low-volume institution? NIH has partnerships with neighboring institutions, but if fellows do not spend 51 percent of their time at NIH, then their experience does not fall under the NIH ACGME accreditation. Some physicians “moonlight” to keep up their skills. Dr. Masur suggested the possibility of having the hospital provide retention bonuses or other incentives to staff who adhere to standards.
- Dr. Tuckson pointed out that the hallmarks of quality in medicine are transparency, tracking, monitoring, and rigorous follow-up of any deficiencies. He asked for a copy of the measures being used in the Clinical Center. Given that the Clinical Center is a low-volume hospital with an unusual patient population, it might be challenging to compare data against other institutions.

**Follow-Up Item:** Forward to the CCRHB a copy of all measures being used in the Clinical Center, not just the aggregates. The CCRHB would like to assess the baseline situation and then determine whether some measures need to be tweaked because this is a low-volume hospital. What are the right measures in this special facility?

- Mr. O'Neill referred to the governance structure and financial issues and asked about the extent to which Dr. Collins has discretionary control to implement changes. Dr. Collins explained that some changes in the governance structure are in the works, but when it comes to financial issues, NIH does not have any discretion; Congress has to get engaged. Nor does NIH have the salary control to attract the necessary staff.
- Mr. O'Neill remarked that the Clinical Center's budget exceeds the budget of many of the ICs. Nevertheless, it is challenging that the customers (i.e., the ICs) can demand more but the Clinical Center lacks the power to acquire more resources. He suggested that the Secretary of the Department of Health and Human Services might be in a position to advocate for a separate line item for the Clinical Center. Dr. Collins said that this is a very important, yet complicated issue. Although a line item sounds like a solution, there are significant risks. Congress could then decide each year how much to allocate. With the current situation, NIH leaders have some flexibility to set the budget for the Clinical Center without depending on the whims of a political process. Fixing the problem would require the support of the Office of Management and Budget and Congressional intervention.
- Dr. Collins listed some actions that are underway: hiring a CEO, setting up a CPC, and convening the inaugural meeting of this board. The Clinical Directors will have a direct reporting line to the Clinical Center. Dr. Nath thought that all the Clinical Directors—but perhaps not all the Scientific Directors—would appreciate that connection. Budgetary

authority would still reside with the Scientific Directors. Dr. Masur said that the question is how to get leverage over the providers.

- Dr. Collins noted that the Red Team had recommended that the members of the CPC be involved daily in the Clinical Center at all levels and across disciplines. Is that a model that other institutions have used, and to whom do such committees report? Dr. Forese clarified that the Red Team said to consider establishing such a committee. The idea came up during discussions with different ICs. The committee would include individuals within the organization who could think about cross-disciplinary issues, but not necessarily have authority. The committee would inform the CEO about issues that cross boundaries. Dr. Nath added that the CPC could interact with the MEC but report to the CEO.
- Richard Shannon, M.D., asked about the effectiveness of training programs for this unique workforce at the Clinical Center. Dr. Masur said that the budget is a challenge, as is succession planning for NIH leadership. NIH has a robust training program starting from medical school and extending through residency and postdoctoral fellowships. Trainees benefit from exposure to research. It is disturbing, however, that NIH does not have the funding to bring them on board.

## **Proposed Clinical Center Governance Structure**

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

Dr. Tabak presented a proposed governance structure, which he emphasized is just a model to provide the CCRHB with a framework for discussion. The Red Team noted in its report that “fragmented governance, responsibility, authority, and accountability has led to an unclear locus of responsibility for leadership.” It recommended establishing an outside external hospital board (i.e., the CCRHB) and strengthening leadership authority and responsibility by centralizing authority for clinical research, clarifying responsibilities of Clinical Center leadership, and integrating patient safety in individual performance plans.

Dr. Tabak presented the existing governance structure, including the 27 IC Directors. A subset of the IC Directors comprise the NIH Steering Committee, which advises the NIH Director on administrative and operational issues (but not scientific issues). He also pointed out the new entities that will be added to the structure. The new CEO will be exclusively dedicated to running the hospital. The CCRHB also reports to the NIH Director.

The proposed governance structure included three hypothetical managerial positions in the Clinical Center: the chief nursing officer (CNO), chief medical officer (CMO), and chief operating officer (COO). Leadership would report directly to the CEO. All of the health professionals in the Clinical Center departments would report to the CEO through the CNO and CMO. Clinical Center staff come primarily from the ICs, and they would report directly to the IC Clinical Directors.

Dr. Tabak pointed out that a great deal of clinical activity does not occur within the walls of the Clinical Center. NIH clinical research activities are conducted in a variety of places, including Maryland, North Carolina, and Arizona. Certainly, we want to harmonize the practice of medicine for all NIH medical professionals, regardless of where they are located.

The MEC, which is composed of IC Clinical Directors and others, might report up through the CMO, who reports to the CEO. The main difference between the MEC and the Clinical Practice Committee is that the CPC will be smaller and more nimble for decision-making. The CPC could make recommendations to the CEO.

Dr. Tabak noted that the proposed structure does not include a box for facilities.

He reviewed the proposed governance for safety and compliance elements, which would report to the hypothetical COO position, who would be responsible for day-to-day operations. He observed that several organizations have responsibility for regulatory and compliance issues and suggested that there are opportunities to integrate and harmonize some of these entities.

Another senior position would be the hypothetical chief scientific officer (CSO), who would be responsible for research and academic programs within NIH, primarily focused on the Clinical Center. This position would report directly to the NIH Director, but would also have to interface closely with the COO and have a relationship with the IC Directors.

Two other important roles under the CSO are the Resource Protocol Review Committee and the Sterile Products Request Committee. Resource protocol reviews are necessary for deciding on how to prioritize protocols, based on their relative merit versus the resources required. Comparing across ICs would be a new approach, but the process needs to be fair and transparent. The Sterile Products Request Committee is already in place to help source sterile products since the PDS closure.

Turning to the question of finances, Dr. Tabak said that the Clinical Center CSO would provide input to the Clinical Center Governing Board, which reports to the Management Budget Working Group, as well as the NIH Steering Committee. This particular organization vis-à-vis finances will likely continue in the same form as it does today. Whether the Clinical Center's budget is increased or not, it would still go through this same process.

### ***Discussion***

- Mr. O'Neill suggested thinking of an inverted pyramid when assigning authorities and responsibilities in organizations. As NIH Director, Dr. Collins would be at the bottom. At the top would be the customers and others who need products and services from the Clinical Center. The top line for the Clinical Center would be research. Patients come to the Clinical Center as a consequence of the research. Therefore, the demand is derived from the research function; everything else seems derivative, and several functions are

secondary derivatives. As an intellectual exercise, think about opportunities to simplify the structure and focus on the “customer” and derivative demands.

- When thinking about financial considerations, Mr. O’Neill advised NIH leaders to remember that everything flows from the top line in the inverted pyramid.
- One issue is the role of the federal government in biomedical research, as well as the roles appropriate for nonfederal sources (e.g., academia, industry, state and local health authorities, the World Health Organization)—any entities that are trying to advance the well-being of humanity. What is the optimal level of funding across the board, and what proportion should be funded by the federal government? The ICs were created along the lines of diseases, but allocating funds based on lobbying to Congress might not be the optimal situation.

**Follow-Up Item:** Dr. Collins offered to forward the CCRHB a report issued last September on the roles of government, academia, and industry in research.

“Getting to perfect,” including worker safety, means that every person in the enterprise—those who do the work, not safety experts—has to take ownership.

- Dr. Shannon suggested that the next iteration of the governance structure include mapping of functions in order to identify redundancies. He also discussed customer–supplier relationships, suggesting that the supplier is the Clinical Center and the customers are the ICs. The role of the CSO will be critical for determining the match. If an IC provides funding, it will demand value from the Clinical Center for that investment. How would those demands influence the CSO as he or she balances supply and demand? Dr. Shannon said that research questions will change, so the supplier’s ability to be nimble would be critical.
- Mr. O’Neill spoke about the importance of having a “living and breathing” financial allocation for the Clinical Center. If the hospital has to be “on call,” it needs to keep a core workforce in place. Bad morale results from uncertainty. The ICs need to provide for the marginal cost of dealing with their own protocols. The average daily census can figure into the calculation of how many transporters are needed, for example. Endoscopy is a core function that needs to be in place every day.
- Gary Gibbons, M.D., Director of the National Heart, Lung, and Blood Institute, commented that the Clinical Center is one of the few places in the world where the standard protocol for placing Swan-Ganz catheters calls for use of magnetic resonance imaging. It can be done safely in this research hospital, and using this technology advances science. Dr. Gibbons also said that IC clinicians need to maintain their clinical skills to remain marketable, so some resistance might emerge if procedures were all done by a Clinical Center team.
- A CCRHB member remarked that patients have a right to be assured that clinical interventions are being handled at the highest level of competence. Is it appropriate for clinicians to practice their skills on research participants? They deserve the highest-quality interventions possible. Dr. Gibbons said that clinicians are encouraged to moonlight to keep their skills honed. The NIH ICU and infectious diseases unit are truly

excellent. NIH does not want “research dabblers” here. Douglas Lowy, M.D., Acting Director of NCI, emphasized that the Clinical Center is first and foremost a research hospital. Patient safety and quality of care need to be paramount. Dr. Forese agreed, saying that the business of the Clinical Center is research, but the Center exists for patients.

- Forcing staff to give up surgery or other specialties due to low volume affects NIH’s ability to recruit. This is a critical issue.
- Dr. Masur acknowledged that certain procedures cannot be done in the Clinical Center, and patients are transported elsewhere when necessary. The question is whether NIH should be training physicians to do research or provide clinical care or whether the future of medicine is in the hands of physicians who want to do both. This question needs to be addressed with a funding model so physicians do not risk losing research funding.
- Dr. Shannon said that having a place where physicians can be excellent researchers, teachers, and clinicians provides real value. But, there must be transparency about where gaps in expertise exist in the Clinical Center.
- Dr. Forese recalled a comment about the need for a pediatric ICU. What would have to be foregone in order to support a new ICU?
- Dr. Shannon recommended that NIH leaders assess the available expertise and the gap to figure out how to provide care in areas where expertise is lacking.
- Dr. Clancy speculated that some NIH leaders have probably found the governance structure unwieldy. The proposed governance structure appears to be an attempt to justify what already exists.
- Beatrice Bowie said that NIH takes good care of its patients, but sometimes there is a perception that might not be true.

### **Chief Executive Officer Characteristics**

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

Dr. Forese proposed a list of responsibilities for the new hospital CEO:

- Think about care for and safety of patients.
- Guide the performance of the entire Clinical Center.
- Oversee operations, the entire management team, and leaders on the clinical and operations side.
- Ensure that all accreditation and licensure standards are met.
- Establish analytics to decide what the Clinical Center can and cannot do.
- Think about how to use new resources or shift existing resources.
- Consider the existing gaps in the management team and the capabilities of the staff and their credentialing.
- Develop short- and long-term strategic plans.

Dr. Forese emphasized that the CEO will have to work collaboratively with many different people, including some important leaders. The CEO's vision will have to be explained to the thousands of people who work here and the patients who are seen here. The CEO must have good communication skills, and messaging must be done thoughtfully and clearly but with passion and clear commitment. We need a leader who cares about this institution and its future.

### ***Discussion***

Dr. Forese asked those present about their ideas about experience and background for candidates. What are appropriate demonstrations we should look for? What interpersonal skills will be most important? What sort of background and experience would ensure that candidates have the wherewithal to take on this challenging role?

- The search should not be limited to physicians or other people with clinical backgrounds. Individuals with deep administrative backgrounds could be excellent candidates. It would not make sense to limit the field too much at this point.
- The CEO has the ultimate authority and responsibility in an institution. The CEO would need the power to say, "I know this is great science, but we can't do it. I can't provide what you, the customer, would like me to do, because it can't be done safely."
- Having a CSO would help unburden the CEO position in terms of the required skill set.
- When formulating the requirements for the CEO position, think about the proposed governance: The candidate would need to have clinical knowledge and skill and some familiarity with facility redesign.
- Dr. Collins said that some people have worried that NIH's financial limitations may limit the search for a CEO. Hospital CEOs are highly compensated. NIH cannot be fully competitive. He pointed out that the Clinical Center is a relatively small hospital, but it has special challenges because of the uniqueness of the institution and its mission.
- The CEO should be someone who enjoys advancing science.
- Mr. O'Neill thought that some people would be motivated because of their interest in performing public service.
- Dr. Tuckson thought that some individuals might see the Clinical Center CEO position as a stepping stone to a leadership role at a larger academic medical center.
- The CEO position would be an opportunity for learning skills and building experience. The first CEO will have an opportunity to leave a legacy.
- Dr. Tuckson suggested solidifying the organizational structure to help support the CEO, but others in attendance thought it would be important for the new CEO to have input on the model—especially the question of whether to add the proposed positions of COO, CMO, and CNO.

Several people underscored the importance of getting input from Clinical Center stakeholders, particularly staff and patients. Dr. Tuckson expressed the hope that the new CEO will be committed to hearing and learning from every person in the organization at all levels.

Dr. Forese suggested that the CCRHB members talk to people about this exciting opportunity. Dr. Collins hopes to select the CEO by year's end. The CCRHB believes that things will be helped by identifying this leader.

### **Closing Statement and Adjournment of Open Session**

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

The next face-to-face CCRHB meeting is scheduled for October 21, 2016. Dr. Forese and Dr. Collins thanked the board members for their thoughtful input. Dr. Forese adjourned the open session at 3:01 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 3:30 p.m.

/Laura Forese/

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

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, NewYork-Presbyterian

/Lawrence A. Tabak/

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/Francis S. Collins/

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

Ex-Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

## **Abbreviations and Acronyms**

ACD	Advisory Council to the Director
ACGME	Accreditation Council for Graduate Medical Education
CCRHB	Clinical Center Research Hospital Board
CLABSI	central line–associated bloodstream infections
CEO	chief executive officer
CMO	chief medical officer
CNO	chief nursing officer
COO	chief operating officer
CPC	clinical practice committee
CSO	chief science officer
DSMB	data safety and monitoring board
FDA	U.S. Food and Drug Administration
FY	fiscal year
GMP	Good Manufacturing Practices
ICs	Institutes and Centers
ICU	intensive care unit
IRB	institutional review board
MEC	Medical Executive Committee
NCI	National Cancer Institute
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration

PDS

Pharmaceutical Development Section