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Clinical Center
Engagement Project
Report
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Stewart Simonson

Facilitator

REPORT – ACKNOWLEDGEMENTS

I am indebted to the members of the CC Engagement Working Group, all of whom faithfully participated in Focus Groups and helped me understand the important work that occurs in Building 10.

I would like to thank Stuart Nightingale, MD, my longtime colleague and collaborator, for his work on the CC Engagement Project. His contributions to the Focus Group process and this report are too numerous to list.

Thanks are also due to Cheryl Fisher and Jessica (Kesler) Cene who provided all manner of assistance to Dr. Nightingale and me. The CC Engagement Project benefited mightily from their involvement.

The CC Engagement Project was fortunate to have the support of a number of NIH staff, including Justin Cohen, Debbie Accame, David Saeger, Rachael Schacherer, Cooper McLendon, Kristen Welch, Rebecca Coca, Erica Vass, and Melissa Shue. I appreciate their commitment to the project and their hard work.

Finally, I am grateful to the NIH staff who participated in the Focus Groups or otherwise contributed to the CC Engagement Project. They are the reason the CC is a great research hospital.

REPORT – PREFACE

Background

In April 2016, a Working Group of the Advisory Committee to the NIH Director, also referred to as the Red Team, submitted to the Director a report titled *Reducing Risk and Promoting Patient Safety for NIH Intramural Clinical Research*. In this document, the Red Team stated that "a culture and practice had gradually and unintentionally evolved at the NIH Clinical Center (CC) where patient safety had become subservient to the demands of research."[1] Since staff are dedicated to the CC's mission, and especially its patients, the Red Team's statement had a profound, negative impact on staff morale in Building 10.[2] The Red Team Report contained other findings and recommendations, but it was the assertion that patient safety had somehow become secondary at the CC that evoked the strongest response. Many staff at the CC rejected the Red Team Report outright because of this statement; and, some felt that the Red Team had not consulted sufficiently with the people who know the CC best—the staff who work in Building 10.[3] As part of a concerted effort to address that report and its effect on staff, Dr. Francis Collins, NIH Director, and Dr. Lawrence Tabak, NIH Principal Deputy Director, asked me in July 2016 to facilitate Focus Group sessions for all interested staff at the CC. Following a Town Hall meeting led by Dr. Collins, I facilitated 70 Focus Group sessions with 621 participants between September 2016 and January 2017. In addition to Focus Group sessions, I had numerous one-on-one meetings and follow-up discussions between July 2016 and July 2017 with Focus Group participants, staff within the NIH Office of the Director, and Institute and CC leadership.

Project Objective

The principal objective of the CC Engagement Project was to listen to and seek advice from IRP staff on ways and means to improve the CC. It is important to appreciate that staff who participated in Focus Groups or otherwise contributed to the Engagement Project were entirely self-selected, not a randomized sample. Accordingly, it was not the objective of the CC Engagement Project to undertake a scientific study or an independent audit of clinical operations in Building 10.

Clinical Center Engagement Working Group

To assist me with the Focus Group process, Dr. Michael Gottesman, Deputy Director for Intramural Research, who heads the Office of Intramural Research within the Office of the NIH Director, selected 19 individuals, with substantial CC experience, from the Intramural Research Program (IRP) to serve on what would become the CC Engagement Working Group. A list of members is included in this report in Appendix A. The first Focus Group session was with the CC Engagement Working Group, which helped to shape the structure and format of subsequent sessions. Indeed, the questions I used to facilitate Focus Group sessions arose out of discussions with CC Engagement Working Group members about the best ways to elicit constructive and productive dialog with participants. Members of the CC Engagement Working Group attended most Focus Group sessions and helped me to understand the issues that were raised in these sessions. I met on several occasions with the CC Engagement Working group as a whole

[1] The Clinical Center Working Group Report to the Advisory Committee to the Director, NIH. Reducing risk and promoting patient safety for NIH intramural clinical research: final report. Bethesda, MD: National Institutes of Health, April 2016 (http://acd.od.nih.gov/Red_Team_final_report_4262016.pdf).

[2] Building 10 is the NIH Clinical Center. The Building 10 complex includes the Warren G. Magnuson Clinical Center, the Ambulatory Care Research Facility (ACRF) and the Mark O. Hatfield Clinical Research Center.

[3] Staff who work in Building 10 include staff employed by seventeen NIH Institutes, staff employed directly by the CC and staff employed by NIH OD.

to review and seek comments on draft presentations I prepared for the CC Research Hospital Board and the Advisory Committee to the NIH Director. Finally, I consulted with the CC Engagement Working Group, individually and collectively, during the drafting of this report.

Focus Group Sessions

Following the Town Hall Meeting led by Dr. Collins, a website on the NIH intranet was launched to enable interested staff to sign up for Focus Group sessions. The information collected from submissions to this site was used to schedule and populate the sessions. It is important to appreciate that Focus Group sessions consisted entirely of self-selected, not randomly-sampled, participants. Sessions lasted about one hour. The number of participants varied anywhere from one to 25, with an average of nine participants per session. While sessions were sometimes spirited and animated, Focus Group participants were, without exception, professional and constructive. Participants came well-prepared and eager to engage in a meaningful dialog on ways and means to improve the CC.

Process

The information that forms the basis for this report is the product of 70 Focus Groups and numerous one-on-one discussions with self-selected staff who work in or support the CC. Focus Groups discussions were organized around several questions I developed with input from the CC Engagement Working Group, but each discussion had its own character and offered unique insights into the CC. I considered these discussions and followed up with members of the Engagement Working Group and others at the CC to help me distill what I heard from participants into themes and then synthesize recommendations. This report is, therefore, the product of an inherently subjective process and should be understood in this context.

Briefings and Presentations

Since the project began in September 2016, I have given periodic briefings to NIH officials and made presentations to two NIH advisory committees.[4] As a result of these briefings and presentations, as well as an ongoing review of the CC by NIH and CC leadership, actions have been taken by OD and the CC CEO to address a number of concerns raised in Focus Group sessions.

Report

I began drafting this report shortly after the final Focus Group session on January 3, 2017. With the help of several colleagues, I tried faithfully to distill the issues that surfaced during the Focus Group sessions and then formulate recommendations to address these issues. Since information sharing with staff in Building 10 is often suboptimal and uneven, Focus Group sessions sometimes involved discussions about deficiencies that did not actually exist yet were perceived to exist by participants. While I have tried to accurately represent the substance of Focus Group discussions, I have done my best not to address these items in the report.

[4] Presentations were made to the NIH Clinical Center Research Hospital Board on October 21, 2016 and January 13, 2017; and to the Advisory Committee to the NIH Director on December 9, 2016.

The report is structured around the themes that emerged in the Focus Group sessions. Each theme is following by a corresponding recommendation. I have also included in Appendix D a summary of recommendations with a proposed responsible official for each one.

In an effort to achieve accuracy in drafting this document, I consulted extensively with OD, CC, and Institute leadership as well as the CC Engagement Working Group and other stakeholders. The report was reviewed—and commented on—by NIH Leadership prior to finalization.

Conclusion

In August 2001, I joined the Department of Health and Human Services (HHS) as a Deputy General Counsel with responsibility for the Office of General Counsel's Public Health Division, which includes the Office of the NIH Legal Advisor. At the time, I had no experience with NIH and was not particularly well-informed about the work of the CC. But colleagues in the Office of the Secretary who had come to HHS before me described the CC as being a great hospital and the very heart of the NIH. My experience over the next five years confirmed the accuracy of this assessment. Indeed, some of the most meaningful, important memories from my time at HHS involve the CC.

When Dr. Collins and Dr. Tabak asked me to facilitate these Focus Groups, I was eager to do so and honored to be asked. Since I had substantial experience with NIH, I thought I understood the CC; and, while I knew there were problems facing the CC as there are with any large organization, I did not believe these problems were significant.

The CC that emerged in the Focus Group sessions was, in some ways, different from the place I thought I knew. When the project began, I had little or no appreciation for the complexities of the CC's fragmented organizational structure and the extent of the challenges created by the suboptimal and uneven information sharing practices within the IRP. The declining state of essential infrastructure and equipment the Building 10 complex was a surprise to me, as was the absence of a comprehensive strategic plan for the CC—one developed with involvement of (and financial commitment from) the OD, Institutes, and CC leadership.[5] I learned a lot during this process—much, much more than I had expected.

Thanks to this project, I now feel that I have a better, more realistic understanding of the problems confronting the CC. However, after 70 Focus Group sessions, and numerous one-on-one discussions, I have an even higher opinion of the CC and its staff than I did when this project began in September 2016. There is no other place in the world like the CC. In spite of a fragmented organizational structure, suboptimal and uneven communications, the declining state of infrastructure and equipment, and no comprehensive strategic plan, the CC is a great research hospital. It is a great research hospital with these deficiencies; imagine what could be achieved in Building 10 if they were corrected. I hope this report will help NIH meet the challenges facing the CC and secure its future as America's research hospital.

Stewart Simonson[6]
Washington, DC

[5] The CC does have a Strategic and Operating Plan (see https://clinicalcenter.nih.gov/about/_pdf/2016-17CCOperatingPlan.pdf), but this document was not developed with meaningful input and funding commitments from the 17 Institutes that admit patients to the CC.
[6] See Appendix B for biographical information

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REPORT – EXECUTIVE SUMMARY

In April 2016, the Clinical Center Working Group of the Advisory Committee to the NIH Director submitted to the NIH Director a report titled *Reducing Risk and Promoting Patient Safety for NIH Intramural Clinical Research*. In this document, many important suggestions for strengthening the CC were made; but the Red Team report also stated that "a culture and practice had gradually and unintentionally evolved at the CC where patient safety had become subservient to the demands of research."[7] This statement had a profound impact on the staff at the CC. Many CC staff rejected the report wholesale because of this statement; and, some felt that the authors of the report had not consulted sufficiently with the people who knew the CC best—the employees. A period of low morale set in following the release of that report.

As part of a concerted effort to address that report and its effect on staff, Dr. Francis Collins, NIH Director, and Dr. Lawrence Tabak, NIH Principal Deputy Director, asked Stewart Simonson in July 2016 to facilitate Focus Group sessions for all interested staff at the CC. An email invitation to participate in these sessions was sent to all those who work in the CC and participants were promised that comments would not be attributed to them. Focus Group sessions consisted entirely of self-selected, not randomly-sampled, participants.

Mr. Simonson conducted 70 Focus Group sessions with 621 participants between September 2016 and January 2017 and had numerous one-on-one meetings and follow-up discussions with Focus Group participants, staff within NIH OD, as well as Institute and CC leadership.

To assist with the Focus Group process, a broad spectrum of staff from the NIH Intramural Research Program were identified by the NIH OD and asked to serve on a CC Engagement Working Group to help Mr. Simonson shape the structure and format of Focus Group sessions, and provide advice to him throughout the process. CC Engagement Working Group members suggested the best ways to elicit constructive and productive dialog with participants.

This report describes the perceptions of Focus Group participants and recommendations, formulated by Mr. Simonson, based on Focus Group discussions as well as one-on-one meetings. Focus Group sessions sometimes involved discussions about deficiencies that did not actually exist, yet were perceived to exist by Focus Group participants. In drafting this report, Mr. Simonson did his best not to address those issues.

The report is organized around the following five themes that emerged from the sessions:

Theme 1—Governance, Administration, and Accountability
Theme 2—Quality of Care and Clinical Research
Theme 3—Communications and Engagement
Theme 4—Organizational Development and Human Resources
Theme 5—Clinical Center Facilities, Equipment, and Systems

For each theme, the report provides a Discussion Section and a Recommendations Section. The Discussion Sections consist of numbered paragraphs that succinctly identify concerns raised by Focus Group members. The Discussion and Recommendation Sections are both numbered to make clear which

[7] See Footnote 1.

recommendation is made for each concern raised in that Theme area. The report includes a total of 50 recommendations.

Staff at all levels state that they are dedicated to the CC's unique mission and strive to provide the highest quality of care. They are committed to advancing biomedical research and caring for patients. Although the report describes staff concerns about a fragmented organizational structure, inadequate information sharing, declining infrastructure, and no comprehensive strategic plan, the CC staff state that it is an honor and a privilege to be a part of a place where the frontiers of biomedical knowledge are advanced every day, and they hope that this report will lead to strengthening the CC. NIH leadership have already addressed a number of the concerns raised in Focus Group sessions and, it is hoped that the discussions and recommendations organized by the five themes in this report will help NIH leadership meet the remaining challenges facing the CC.

Since the project began nearly one year ago, periodic briefings have been given to NIH officials and presentations made to two NIH advisory committees that included interim recommendations. As a result of these briefings and presentations as well as an ongoing review of the CC by NIH leadership, actions have been taken by OD and the CC CEO to address a number of concerns raised in Focus Group sessions. A document listing these recommendations and a proposed responsible official for each recommendation is included in this report in Appendix D.

REPORT – FOCUS GROUP DEMOGRAPHICS

Breakdown of Sessions:

General Sessions (49)

Physician Groups (6)

Nutrition (2)

Housekeeping (1)

Staff Clinicians/Fellows (1)

Patient Advisory Group (1)

NIH Legal Advisor (1)

Bioethics (1)

Office of Research Facilities (1)

Office of Human Subject Research Protection (1)

Protocol Navigation Group (1)

CC Vendors (1)

CC Engagement Working Group (1)

Scientific Directors (1)

CC Department Heads (2)

Breakdown of Participants:

Nurses (195)

Physicians (184)

PhD Scientists (30)

Bioethicists (14)

Pharmacists (9)

Social Workers (8)

Laboratory Technicians (6)

Dieticians (5)

Dentists (2)

Physical Therapists (2)

Other (166)

The "Other" category (166) includes; Administration, Food Service, Consultants, Lawyers, Epidemiologists, Chaplain, Genetic Counselors, Patient Advisory Group, Protocol Navigators, Office of Research Facilities (ORF)

REPORT – THE MISSION AND COMMITMENT OF STAFF AT THE CC

To set context for each session, Focus Group participants were asked at the outset what was most gratifying to them about working at the CC, what brought them to the CC, and what keeps them at the CC. The following statements reflect the tenor and substance of responses to this question:

- Staff, at all levels, are dedicated to the CC's unique mission and want to provide the highest quality care to CC patients.
- There is no other place in the world like the CC: the bench-to-bedside research environment and the resources available to investigators make the CC a biomedical research institution without peer.
- Working at the CC provides a unique opportunity to care for patients in an environment focused on clinical and research excellence, not cost or other factors ordinarily associated with third-party healthcare programs.
- Patients who come to the CC participate in the advancement of biomedical science; and, staff are dedicated to giving these patients the best possible care.
- Investigators at the CC are among the world's experts in their fields, making the CC an intellectually stimulating environment in which to work.
- Staff feel a genuine connection with patients and their families, many of whom have been coming to the CC for years.
- It is an honor and a privilege to be part of a place where the frontiers of biomedical knowledge are advanced every day.

This initial question consistently evoked strong, and often moving, expressions of commitment to the mission of the CC and the care of its patients. Focus Group participants with even an attenuated connection to research often evinced pride in the scientific achievements of their colleagues. Throughout the 70 Focus Group sessions, participants at all levels of the organization indicated that providing the highest quality patient care is what matters most to them in the performance of their duties at the CC.

REPORT – PATIENT SAFETY AND CLINICAL RESEARCH AT THE CC

Focus Group participants were asked four questions about patient safety and clinical research:

- What tension, if any, do you observe between patient safety and clinical research at the CC?
- How, if at all, does the unusual (for a hospital) organizational structure of the CC affect patient safety?
- What, if any, concerns related to patient safety weigh on you?
- If you could change one thing at the CC to improve patient safety, what, if anything, would you change?

In response to these questions, the following five themes emerged:

- Theme 1—Governance, Administration, and Accountability
- Theme 2—Quality of Care and Clinical Research
- Theme 3—Communications and Engagement
- Theme 4—Organizational Development and Human Resources
- Theme 5—Clinical Center Facilities, Equipment, and Systems

Focus Group participants provided their views on patient safety and quality of care. They also discussed their experiences with the tension between research and clinical care at the CC. They provided recommendations for improvements in the CC and Institute clinical activities related to the CC as well. It was noted that there was widespread variability in clinical and research practices throughout the CC and the issues identified were not occurring uniformly across the CC. Focus Group participants were asked not to make recommendations related to appropriations, budget, Federal hiring policies, and Federal procurement policies, but issues related to these areas came up in discussions and are noted in the report.

Theme 1—Governance, Administration, and Accountability

Discussion:

1.1 The CC provides the infrastructure and hospital services to support 17 of the 27 Institutes and Centers that make up the NIH IRP. The CC CEO does not currently have sufficient authority over Institute activities at the CC, creating governance challenges on several levels and fragmentation of services between and among Institutes and the CC. Although there is an annual Strategic and Operating Plan developed by the CC, it is not comprehensive and does not adequately address Institute activity at the CC. Since the 17 Institutes do not participate in the development of this strategic plan, it does not address funding requirements for the CC. There was a strong consensus among Focus Group participants that the CC is not resourced properly to perform its core mission, and the School Tax[8], as currently constituted and applied, is insufficient to meet the needs of protocols approved for the CC at its optimal census. The School Tax funding model, in its present form, is poorly suited to keep up with CC expenses. Previous funding models have been tried but were not sufficiently tailored to the mission of the CC and, accordingly, were unsuccessful.[9]

1.2 With 17 Institutes competing for resources within the CC, each with independent budget authority, distinct areas of focus, and no real accountability to the CC CEO, the result is a fragmented environment that has a negative impact on processes and efficiency in Building 10. Participants acknowledged that they deal with this fragmentation by so-called work-arounds, and an enormous amount of time and effort is invested to ensure that patients receive the care they need. The fragmentation also results in variability in practice across the CC, of which both staff and the patients are aware.

1.3 The NIH Office of Research Facilities (ORF) is a part of and reports to the NIH OD. Since infrastructure priorities do not always align between OD and the CC, this can lead to problems at the CC, including those impacting quality of care and patient safety. There was a consensus among Focus Group participants that the CC CEO should be empowered to set ORF priorities for the hospital with quality of care and patient safety as the primary considerations. Participants also felt the CC CEO should be empowered to hold ORF accountable for the quality and timeliness of work undertaken at Building 10.

1.4 Focus Group participants noted that the OD functions led by the NIH Deputy Director for Intramural Research and the NIH Deputy Director for Management significantly impact CC operations. The CC CEO does not currently participate in the annual performance assessment of these two OD officials. This absence of formal input by the CC CEO in the annual assessment of these two officials appears to be an indication of NIH's stove-piped approach to CC management.[10]

1.5 There is wide variability in practices at the CC compared with what are established as Standard Operating Procedures (SOPs) in other hospitals. Focus Group participants described the hospital as functioning in silos. This appears to be, in part, because certain drivers for consistent adherence to SOPs in other hospitals are related to the healthcare reimbursement system, which requires compliance with

[8] A funding structure in which the CC is supported by an annual contribution of funds from each IC that is proportional to its overall budget.

[9] Unlike NIH OD and each Institute, the CC does not receive its own appropriation from Congress. As a result, the CC must rely on OD and the Institutes for funding. Under the School Tax model, there does not appear to be a preferential option for the CC, rather the CC must compete for funding with OD and Institute priorities.

[10] Focus Group discussions related to these issues were supplemented by one-on-one discussions.

specified SOPs for payment to occur. These requirements do not apply to the CC, which does not participate in the reimbursement system. Pre-admission forms for Institutes (evidently each Institute has its own form), patient discharge, and transfer and handoff to outside facilities are not standardized processes. The result of this lack of standardization sometimes results in confusion among staff and additional time spent trying to learn or keep up with each Institute's practices.

1.6 Inadequate documentation in the electronic medical record was also raised by Focus Group participants on multiple occasions as creating problems for patient care teams and consult services. Instances of incomplete medical records, inaccurate medical records, and a lack of consistency about where notations are made in the charts were described in Focus Groups as problematic and having the potential to impact quality of care and patient safety.

1.7 It was noted during Focus Group discussions that Institute programs at the CC are not comprehensively and regularly evaluated by the CC CEO for patient safety, quality of care, volume of activity, quality of training, adequacy of research support, and stakeholder satisfaction.

1.8 Focus Group participants in several sessions suggested that the membership and terms of reference of the CC Medical Executive Committee (MEC) is not optimal for dealing with issues of patient safety and quality of care. The MEC largely consists of CC leadership and Institute Clinical Directors. A number of Focus Group participants felt that the MEC should include more members with closer contact with day-to-day patient care at the CC.

1.9 A number of participants raised questions about the scope of authority, responsibility, and practices of the MEC. Some stated that it is not properly organized to meet the needs of the CC. Concerns were raised that decisions made by the MEC are not communicated effectively to CC staff.

1.10 Some Focus Group participants were concerned that credentialing by the MEC was essentially an automatic ratification of what is proposed by Clinical Directors for their Institute's Principal Investigators (PI). The sense of these participants was that MEC's credentialing process should be more rigorous and less deferential to Institutes.

1.11 Variability in PI clinical capabilities was also identified as a concern by Focus Group participants. Some investigators rarely see patients and may not keep up with current standards of clinical care, yet may still be medically responsible for patients. PI clinical capabilities are assessed by Institute Clinical Directors, who may not always be close enough to day-to-day patient care to make such a determination.

1.12 Some Institutes were described as having best practices in dealing with Occurrence Reporting System (ORS)[11] submissions, staff communications, and morbidity and mortality management, but these best practices are not widely shared, or consistently shared, among Institutes and, accordingly, there is little consistency in practice across Institutes. Holding staff accountable is difficult due to the fragmented structure of the CC. Further, variability was noted within various branches of Institutes. Thus, a lack of consistency for processes or oversight/accountability is an intra-Institute problem as well as a problem across Institutes. Focus Group participants identified this challenge when discussing the insufficient authority of the CC CEO over operations and management of clinical activity in Building 10.

1.13 Focus Group participants identified issues pertaining to lag time in on-call responsiveness for clinical issues, including the reporting of critical lab values and other clinical needs. Various reasons were

[11] ORS has since been replaced with a new system called the Safety Tracking and Reporting System or STARS.

identified for this lag time, including the difficulty in identifying the appropriate medically responsible person.

1.14 The IRP has 12 Institutional Review Boards (IRBs) responsible for approving, monitoring, and reviewing biomedical research involving humans. Although a committee exists in which all the chairs of the IRBs meet monthly to discuss issues, the IRBs continue to function independently, with different core policies, procedures, and practices for reviewing protocols. Participants noted concerns about inconsistencies among IRBs related to informed consent forms, the complexity of such forms, and subject recruitment procedures.

Participants indicated that CC Departments need to be better consulted on research protocol requirements prior to approval by an IRB because, at times, the resources at the CC are not sufficient to handle, in a timely manner, both protocol requirements and clinical care needs that arise. Currently there is a process to undertake a Protocol Resource Impact Assessment (PRIA). While this assessment is supposed to occur prior to IRB approval, this is not always the case. Furthermore, even when a PRIA does occur prior to IRB approval, the assessment is not sufficiently in depth. For example, the PRIA does not consistently take into account the volume and time sensitivity requirements of a particular intervention or test.

1.15 It was noted during Focus Group discussions that the Department of Perioperative Medicine (DPM) and the Interventional Radiology section of the Department of Radiology and Imaging Sciences (RADIS) nursing staff do not report directly to the CC Nursing Department (CCND), thereby missing important communications and educational opportunities provided to CCND staff. Although nurses outside of the CCND are credentialed by the CCND, the CCND is not directly responsible for providing oversight of their competency training. Fragmented care was also noted in the clinic areas where Institute staff (physicians and research nurse coordinators), CCND nurses, and Patient Support Services Department (PSSD) administrative support all function together, but do so under different reporting structures. The resulting fragmentation within the clinic areas of the CC has the potential to impact quality of care.

Recommendations:

1.1 The NIH Director, the newly appointed CC CEO[12], the newly appointed CC Chief Scientific Officer (CSO)[13], and Institute Directors should jointly develop a multi-year strategic plan for the CC that addresses the following:

- An organizational structure for the CC that empowers the CC CEO to manage the hospital with clear lines of authority and accountability;
- Human capital development and retention at the CC;
- Infrastructure and equipment requirements of the CC;
- Metrics of success for the CC, including optimal inpatient and outpatient census, research productivity, patient safety, training, and compliance with applicable regulatory requirements;
- Metrics of success for inpatient and outpatient clinical services and departments at the CC; and,
- Metrics of success for Institute clinical research programs at the CC.

[12] The position of CC CEO was created in mid-2016 to replace the discontinued position of CC Director. James Gilman, MD, was selected as the first CC CEO in December 2016.

[13] The position of CC CSO was created in mid-2016. It is an entirely new position. John Gallin, MD was selected as the first CC CSO in August 2016. Dr. Gallin also holds the position of NIH Associate Director for Clinical Research.

The strategic plan should include specific funding commitments from OD and the Institutes aligned with the above.

1.2 Institute Directors should delegate to the CC CEO authority over Institute personnel and activity at the CC impacting quality of care and patient safety.

1.3 The NIH Director should grant authority to the CC CEO to set ORF priorities at the CC as well as authority to hold ORF accountable for the quality and timeliness of work undertaken at the CC.

1.4 The NIH Director should obtain from the CC CEO an annual written assessment on the CC-related performance of the NIH Deputy Director for Intramural Research and the NIH Deputy Director for Management and provide same to the NIH Principal Deputy Director, who is responsible for annually reviewing these two positions.[14]

1.5 The CC CEO should develop uniform admission and discharge procedures and basic documentation requirements for all CC patients.

1.6 The CC CEO should be empowered by the NIH Director and Institute Directors to hold all staff who work in the CC accountable for meeting minimum standards of documentation in the medical record that have been established for the CC by the CC CEO. Medical records should then be monitored regularly to assure completeness and accuracy.

1.7 In the annual performance evaluation of each Institute Director with responsibility for research at the CC, the NIH Director should include an assessment of such Institute's CC program, including patient safety and quality of patient care, inpatient and outpatient activity, and quality and extent of services provided at the CC, each informed by a written assessment by the CC CEO.

1.8 The CC CEO should consider revisions in the membership and bylaws of the MEC to ensure better representation of staff with expertise in clinical care at the CC (e.g., staff clinicians) to balance the expertise in research now present among members of the MEC.

1.9 The CC CEO should review the scope of authority set forth in the bylaws of the MEC as well as its practices and procedures to ensure that the MEC is properly constituted, organized, and managed to meet the needs of the CC, including patient safety requirements.

1.10 The CC CEO should review the credentialing process at the CC to ensure medical staff are authorized to perform only those procedures in which they have appropriate training, experience, and demonstrated proficiency.

1.11 The NIH Director should require that each Institute Director with responsibility for research at the CC, along with the Scientific Director for such Institute, to go on clinical rounds with their respective CC staff at least once per quarter.

1.12 To the extent consistent with the multi-year strategic plan discussed in 1.1 above, the NIH Director and Institute Directors should delegate authority to the CC CEO for clinical, administrative, and

[14] Essential functions at the CC are controlled or impacted by offices accountable to the Deputy Director for Intramural Research (e.g. Office of Human Subject Research Protection, Office of Research Support and Compliance, Office of Animal Care and Use, Office of Intramural Training and Education) and the Deputy Director for Management (e.g., Office of Research Facilities, Office of Human Resources, Office of Research Services, Office of Acquisition and Logistics).

operational activity (personnel, space, facility management and maintenance, facility construction, equipment acquisition and maintenance) that occurs within the clinical areas of the Building 10 complex, whether such activity is performed by Institute staff or NIH OD staff. This delegation should include authority to hold Institute staff accountable for timely and appropriate follow-up to ORS (now STARS) submissions. In exercising this authority and as a mechanism to enhance consistency at the CC, the CC CEO should identify best practices among Institutes that might be suitable for CC-wide application.

1.13 The CC CEO should be empowered by the NIH Director and Institute Directors to hold Institute leadership and staff who work in the CC accountable for inpatient and outpatient services, including timely on-call responsiveness and availability.

1.14 The NIH Deputy Director for Intramural Research should establish uniformity in core IRB procedures and policies.

1.15 The CC CEO should consider moving DPM and Interventional Radiology nurses to the CCND.

Theme 2—Quality of Care and Clinical Research

Discussion:

2.1 The CC is a research hospital, not a general hospital. All patients are admitted to the CC under a protocol, as opposed to an admitting diagnosis for treatment. As a consequence, some capabilities present at general hospitals are absent from the CC entirely or not available in a timely manner during off-hours (e.g., interventional neuroradiology, interventional cardiology, vascular and orthopedic surgery, critical care for pediatric patients under 3 years of age[15]). This can complicate care when patients develop conditions that require these capabilities.

2.2 Focus Group participants with experience as clinical investigators indicated that there is substantial variability across Institutes in research support services available to investigators. For example, there is no consistent support at the CC for case managers, protocol navigators, study coordinators, or data monitors. Some Institutes provide these services to investigators and some do not. Participants felt that the absence of these support services for investigators could negatively impact the quality of care as well as research at the CC.

2.3 Some Focus Group participants felt that there is little or no tension between research and clinical care. Other participants stated that at times tension exists and provided examples of situations in which they experienced or observed tension related to difference in priorities between research and clinical staffs that had the potential to impact quality of care and patient safety. One example involved situations in which a patient might need standard of care treatment that would require the PI to take the patient off the protocol. The latter occurs when a patient might need an intervention that would conflict with the protocol. A number of Focus Group participants noted that the Department of Bioethics was instrumental in resolving conflicts or tension between research and clinical care. The Department of Bioethics consults are seen by Focus Group participants as an invaluable resource at the CC.

Sometimes there are short-term delays in treatment in order to determine if other effective therapeutic options might exist that would permit keeping the patient on the protocol rather than require the patient's removal from the protocol.

Focus Group participants noted that decisions regarding care at the CC are, at times, influenced by the patient's unfavorable circumstances (e.g., usual care has failed, lack of healthcare insurance). For example, if giving a medication for standard of care would result in removing the patient from the protocol, some patients, with a full understanding of the potential risk and no other option for treatment, will request to stay on the protocol.

2.4 Focus Group participants noted that the impact of inadequate coverage, lack of full services, and variable standards of care has the potential to create vulnerabilities for high-risk/low volume patients at the CC, especially during off-hours. Appropriate acute care services may be delayed, either because there are no relevant experts on staff or because the full complement of services available in a general hospital is lacking at the CC. Off-hour, non-critical problems are sometimes addressed the next day.

2.5 A deficiency noted by Focus Group participants involves healthy volunteers who participate in multiple protocols. There is no single mechanism or system that tracks the cumulative impact of participation in multiple studies on such healthy volunteers.

[15] Children under 3 years of age and 15 kilograms ordinarily are not admitted as inpatients at the CC.

2.6 Some participants stated that CC policies and procedures are not readily available or accessible to all staff, especially staff employed by Institutes or NIH OD. There was a consensus among Focus Group participants that the CC is a siloed, fragmented enterprise. Participants felt that the CC would be a much stronger, better hospital if there was a greater emphasis on consistency and collaboration among NIH OD, the CC, and the 17 Institutes that utilize the CC.

2.7 Since CC policies and procedures are not well disseminated or readily accessible, participants observed that adherence to these policies and procedures is uneven and suboptimal. This situation is complicated by Institute-specific policies and procedures impacting patient care at the CC.

2.8 Some Focus Group participants felt that an online training platform is needed for the CC to help ensure that staff stay current on clinical care developments and meet all mandatory training requirements. Although there is a Learning Management System (LMS) offered by the Department of Health and Human Services (HHS), it was described as cumbersome, difficult to use, and not well-suited for medical training. The HHS LMS also has a relatively high entry barrier (e.g., costs and training requirements).

2.9 Nursing staff focus on the clinical care of the patients, but, according to some participants, are not consistently informed or briefed by Institute staff on the research requirements of their patients' protocols, potentially impacting protocol fidelity. With multiple Institutes admitting patients to CC units, participants indicated it is difficult to know all the details of every protocol for every patient on the unit, especially when protocol in-service briefings for staff have not occurred. This complexity is compounded by the utilization of supplemental staff (e.g., per-diem and contract nurses) to fill in for the CCND nurses when additional nursing support is required.

2.10 Since the CC is not a general hospital, some capabilities that may be needed to care for patients are not resident at the CC (e.g., orthopedic surgeons, vascular surgeons). Focus Group participants noted that these gaps are often filled on an *ad hoc* basis.

2.11 The CC is a research hospital, and an essential part of its mission is to improve the prevailing standards of care in medicine. In many circumstances, the hypothesis being tested in a research protocol requires a novel therapy or intervention. By definition, a novel therapy or intervention is not the prevailing standard of care. In contrast, there are medical events or conditions that sometimes develop in patients during a research protocol that are not integral to the hypothesis being tested in the protocol. These conditions ordinarily should be treated according to the prevailing standard of care. Focus Group participants suggested that there may be confusion at the CC and among intramural investigators about the circumstances in which the prevailing standards of care apply. Participants felt that there is a need to provide uniform guidance and training to staff on circumstances in which the prevailing standards of care should apply at the CC.

2.12 Focus Group participants identified the emergency transfer of CC patients to area general and specialty hospitals (e.g., Suburban Hospital and Children's National Medical Center) as an often unnecessarily slow and cumbersome process. Where Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) capabilities are needed for such transport, an outside ambulance (e.g., Montgomery Country Fire and Rescue Service ambulance) must be called and then cleared by NIH perimeter security. It was noted that this process could delay ambulance arrival at the CC by as much as 45 minutes.

If patients need care that requires transfer to another facility, there is hesitation for a variety of reasons beyond needing to identify and contact the responsible PI. For example, delays in transfers to a general hospital or a specialty hospital can occur when a patient does not have health insurance and the Institute responsible for the patient has insufficient resources to pay for outside care.

2.13 There is an insufficient number of transport nurses at the CC (i.e., ACLS and PALS certified nurses who specialize in the emergency transportation of patients) to cover the hospital 24/7. As a result, CC transport nurses cannot be reliably leveraged to augment capabilities of the NIH Fire Department's Basic Life Support (BLS) ambulance for inter-hospital emergency transfers. When ACLS or PALS capabilities are required for an inter-hospital transfer from the CC, an outside ambulance is used. As noted above, this can result in significant delays.

2.14 Several Focus Group participants noted that the CC is not *Magnet* recognized by the American Nurse Credentialing Center (ANCC). This program is known to attract and retain nurses seeking employment in an organization demonstrating the highest quality and safety standards and exemplary professional practice. Achieving *Magnet* recognition could facilitate CC nurse recruitment.

2.15 During Focus Group discussions it was noted that nurses are sometimes pulled away from bedside care of patients to pick up medications from the pharmacy or to get supplies from other areas of the hospital due to insufficient support staff.

2.16 Some Focus Group participants thought that quality of care and patient safety at the CC could be improved by providing CC staff with training on identifying and reporting protocol deviations and unanticipated events. Additionally, some participants noted that new fellows and new clinical staff may not consistently be made aware of the services offered by the NIH Office of Human Subject Protection (OHSRP) or the CC Department of Bioethics. The online platform noted in 2.9 above was thought to be one way of offering this training to staff.

2.17 Some Focus Group participants see the CC as actually being 17 different hospitals, each run by a different Institute. Frequent comments were that the CC lacks what general hospitals have as a matter of course: Departments of Medicine, Surgery, etc., that oversee the operations of staff in their specialty. Since every patient at the CC is on at least one protocol, and some are on multiple protocols, it was noted by the Focus Group participants that it can be very difficult to identify the medically responsible physician at any particular time. Identification of the medically responsible person for many patients becomes an issue when staff need clinical decisions to be made or when information from a lab or consult service needs to be conveyed promptly so that action can be taken. This is particularly difficult during off hours (nights, weekends, and holidays). If a clinical fellow entered an order for a consult or lab work, for example, and the results required follow-up by a physician, the clinical fellow placing the order may have been covering at the time but is now not available, or may have left the NIH altogether. Focus Group participants reported an inordinate amount of time spent tracking down the medically responsible person for certain patients.

2.18 It was noted during Focus Group discussions that there are problems at the CC with the movement of clinical and research specimens. In particular, participants indicated that specimens sometimes are sent to the wrong lab, get lost, or are not picked up in a timely manner from the units or procedure areas. This results in specimens (including difficult to obtain biopsies) not being processed in a timely manner or at all. Tests then need to be repeated and delays in treatment can occur. For patients who are not local, and especially when invasive tests have to be repeated, this can create a serious hardship for the patient. To avoid this, clinical staff often personally walk specimens to the correct lab.

Recommendations:

2.1 The CC CEO should seek funding to enhance services provided by Institutes, such as hospitalists with categorical expertise in the areas they would be covering. Such hospitalists might include those with expertise in general pediatrics, pediatric anesthesia, pediatric critical care, or multi-institute clinical programs such as that for stem cell transplantation. The objective of this funding should be to ensure the quality of inpatient, outpatient, and consultative services at the CC. Formal surveys and targeted operations reviews should also be considered as means of evaluating quality of care, patient safety, and support for research and training for American Council of Graduate Medical Education (ACGME) fellows.

2.2 The NIH Director should commit funding for additional and uniform support to clinical researchers across the CC (e.g., for investigator training, protocol navigators, medical writers, study coordinators, data management/statistical support) as well as to utilize independent monitors for protocols to ensure objective reporting and regulatory compliance.

2.3 The CC CEO should develop a CC-wide process for dealing with differences of opinion between staff when patient management issues conflict or do not align with research objectives. Best practices currently employed by some Institutes for addressing these differences of opinion should be considered by the CC CEO in developing the recommended CC-wide process.

2.4 The CC CEO should develop mechanisms to provide appropriate expertise for the conduct of high-risk, low volume procedures at the CC. This may require obtaining specialty consultation or intervention support from outside the CC (e.g., Walter Reed National Military Medical Center, Children's National Medical Center, Suburban Hospital).

2.5 The CC CEO should develop and implement a system to better track the frequency and volume of research blood draws and imaging tests, especially for patients in multiple protocols and healthy volunteers, to assure that established limits for research blood volume and radiation exposure guidelines are not exceeded.

2.6 The CC CEO should harmonize CC policies and procedures applicable to all CC functions whether performed by CC, NIH OD, or Institute staff.

2.7 The CC CEO should require that training on CC clinical policies, procedures, and quality of care and patient safety matters be provided annually to all those involved in clinical care, and that compliance with such requirements be tracked by supervisory staff.

2.8 The CC CEO should provide (or, if insufficient funds are available within the CC budget, seek) funding for CC access to an electronic centralized learning system in order to help staff stay current on clinical care developments and ensure compliance with mandatory requirements.

2.9 The CC CEO should provide (or, if insufficient funds are available within the CC budget, seek) funding to reduce dependence on per diem and contract nurses who are not familiar with CC policies and procedures, especially in high risk areas such as critical care, oncology, and services which provide stem cell therapies. The CEO should also identify best practices among institutes for protocol briefings for nursing staff and consider adopting a CC-wide policy on protocol briefings based on these best practices.

2.10 The CC CEO should develop mechanisms to reliably and at short notice use outside providers to address gaps in clinical services that cannot readily be filled by intramural resources. Such mechanisms might include Interagency Agreements with the Department of Defense (DOD) and Department of

Veterans Affairs (VA), or contracts with Suburban Hospital, Children's National Medical Center, and other area healthcare facilities. These mechanisms should be designed to reliably provide the CC with needed clinical services on a 24/7 basis.

2.11 The CC CEO should develop guidelines for all staff who practice at the CC, including Institute staff, on circumstances in which the prevailing standards of care apply and circumstances in which such standards of care do not apply. All staff should be trained in the guidelines and held accountable for compliance with them. The CC CEO should also make didactic and training opportunities available to staff to maintain their knowledge and experience in practicing standards of care. The selection of a Chief Medical Officer for the CC is likely to be a meaningful step in addressing confusion concerning applicability of prevailing standards of care at the hospital.

2.12 The NIH Director and CC CEO should establish procedures to ensure that ambulances coming to the NIH for emergency transfers from the CC are expedited through campus perimeter security.

2.13 The CC Chief Nursing Officer (CNO) should appoint a sufficient number of transport nurses certified in ACLS and PALS to facilitate and accompany 24/7 emergency transfers from the CC that utilize the NIH Fire Department's BLS ambulance.

2.14 The CC CNO, with the support of the CC CEO, should seek *Magnet* recognition from the American Nurse Credentialing Center (ANCC) for the CC. *Magnet* recognition would help to validate the CC's commitment to quality of care and patient safety. *Magnet* recognition would likely be useful in recruiting and retaining CC nurses.

2.15 The CC CEO should improve administrative support for patient care services to enable floor nurses to focus more of their time on patient care (e.g., sufficient support staff should be available so that floor nurses do not need to leave their patient care duties to carry out administrative activities).

2.16 The CC CEO should consider providing small group educational sessions on event reporting (e.g., reporting of unanticipated problems, protocol deviations, and non-compliance at the NIH).

2.17 The CC CEO should consider creating communities of practice at the CC (e.g., pediatricians, cardiologists, surgeons, internists, psychiatrists, CRNPs, CRNAs) to provide a greater degree of cohesion and professional support for staff who work in these specialties and advanced practice areas.

2.18 The CC CEO should undertake a review of policies and procedures related to the movement of specimens at the CC to ensure such policies and procedures are appropriate and effective. The CC CEO should hold all staff (whether employed by the CC or Institutes) accountable for following existing or revised policies and procedures related to the movement of specimens at the CC.

Theme 3—Communications and Engagement

Discussion:

3.1 Impediments to information sharing related to important issues were identified by Focus Group participants as occurring within Institutes, among Institutes, and between Institutes and the CC. While there are a number of NIH and CC publications and ListServs, there appears to be a gap between what information is shared with Building 10 staff and what staff feel they need.

3.2 Communications issues raised by Focus Group participants included insufficient transparency related to misadventures and unexpected events at the CC, being unaware of important safety-related events at the CC, lack of regular CC morbidity and mortality rounds, being unaware of services offered by the CC for patients, or how to properly access such services (e.g., stroke consult service), procedures for transfer to other hospitals, and other existing CC policies and procedures. Several stated that they were frustrated by learning about CC patient-safety related events first from the news media, as has happened several times in the past year. Frustration was also voiced over communication failures regarding sediment in the CC water pipes following a county water main break, which impacted the building and patient and staff drinking water.[16]

3.3 While there are many NIH, IRP, and CC publications and ListServs, a number of Focus Group participants indicated that they felt they did not receive timely information about important matters related to patient safety and clinical care. Some progress has been made on this with the new *Clinical Safety Rounds* publication, but more could be done to improve communication in this area. Several participants thought *Clinical Safety Rounds* should come from the CC CEO and not the NIH Deputy Director for Intramural Research. A substantial number of participants indicated that the Focus Group sessions were the first time they had an opportunity to express their concerns about the CC in a facilitated and safe setting. Many felt that periodic Focus Groups and regular town hall-like meetings would be helpful in bridging the communications gap at the CC.

3.4 Focus Group participants stated that there is no consistent feedback provided to staff on submissions to the ORS. Participants said that it sometimes felt like their ORS submissions simply disappeared into the ether. Some Institutes do review ORS submissions with staff but that was not the case with others. Also, some participants felt that more could be done to provide feedback and remedial information arising from reports to the CC safety line. There was a consensus among Focus Group participants that some Institutes are proactive about ORS submissions and others passive or even unresponsive.

3.5 A lack of consistency in the ability to contact the responsible medical provider through pagers and cell phones has sometimes led to delays in care and, on occasion, a failure to contact the correct medically responsible person. There appears to be no consistent and reliable procedure or practice to notify the page operator about who is on-call or covering for a particular unit or service. This is compounded by the prevalence of obsolete and ineffective communications equipment at the CC. Focus Group participants indicated a significant amount of time and effort is sometimes expended reaching the responsible medical provider, especially at night and on weekends.

3.6 Focus Group participants felt that it is important for NIH leadership to communicate efforts and

[16] In 2016, a major Washington Suburban Sanitation Commission water main break occurred, and in response, a hospital in the area flushed its system, but NIH facility staff did not, resulting in downstream consequences to the CC and its sensitive equipment.

actions taken in response to the Red Team report. Participants also felt that NIH leadership may be insufficiently proactive in communicating accomplishments and other positive news about the CC.

Recommendations:

3.1 The CC CEO should consult with a cross section of staff who work in the CC (whether employed by the CC, Institutes, or NIH OD) to develop a comprehensive communications plan for intramural staff involved in patient care at the CC. The objective of this plan should be to improve the quality and accessibility of information shared with staff in Building 10.

3.2 The CC CEO should increase the frequency and staff awareness of morbidity and mortality review conferences at the CC; improve reporting to staff about the disposition of misadventure and unexpected events at the CC; require annual training of staff on CC policies, procedures and services (e.g., stroke consult service); and develop a communications algorithm or other mechanism to ensure that CC staff learn about important events and occurrences directly from NIH or CC leadership.

3.3 The CC CEO should establish quarterly Town Hall meetings and establish an on-going focus group/engagement process.[17]

3.4 The CC CEO should ensure that feedback is readily available to all those who make submissions to the ORS (now STARS).

3.5 The CC CEO should commit (or, if insufficient funds are available within the CC budget, seek) funding and ensure accountability for unified telecommunications systems, policies, and processes for all patient care staff working at the CC.

3.6 NIH OD and the CC should develop a proactive strategy to communicate CC improvements and success stories (historical, recent, and current) to NIH staff and external stakeholders using electronic methods such as websites and email as well as physical displays in public areas of the hospital.

[17] In his seven months as CC CEO, Dr. Gilman has held one Meet the CEO session and one CC Town Hall meeting for all Building 10 staff. Dr. Gilman has stated that these Town halls will be held quarterly.

Theme 4—Organizational Development and Human Resources

Discussion:

4.1 It was noted by Focus Group participants that the CC does not consistently or adequately address succession planning or professional development for key staff (a commonplace challenge in the Federal government). Ongoing and consistent professional development at the CC is especially important since the high risk/low volume phenomenon can result in a loss of technical skill for some staff.

4.2 Focus Group participants also observed that the research focus has shifted as new discoveries are made regarding disease progression and investigators seek to study patients at younger ages. This presents a challenge for the CC since it may not have the resources or experts available to intervene if emergency care is necessary for pediatric patients. Multiple concerns arose during Focus Group sessions about inadequate resources across many disciplines and departments for pediatric patients.

4.3 Focus Group participants were concerned that the HHS hiring system can take up to one year to bring in new specialized staff and reported that in one lab area staffing was down by 50%. Cell processing and specialized nursing (e.g., pediatric ICU clinical nurse specialist) require personnel with specific qualifications. Some of these positions have been vacant for an extended period of time. Some participants felt these delays impacted quality of care when contract nurses were needed to fill in or when lab technicians were covering multiple vacancies. The impediment to swift hiring actions is unclear to participants, but there was consensus that more attention needs to be paid to addressing vacancies at the CC.

4.4 A number of Focus Group participants noted that the HHS process for hiring clinical and technical personnel was cumbersome and impeded recruitment of specialized healthcare professionals. Many specialized physician and non-physician clinical and technical personnel are difficult to hire and retain because of the HHS salary scale and, if they leave, very hard to replace. A similar challenge is also faced by the VA and DOD. Participants thought the VA had addressed this problem successfully through a more attractive salary scale for physicians. It was noted that the CC has been able to incorporate VA salary flexibilities for physicians in some scarce medical specialties. Some Focus Group participants thought that the applicability of the approach used in the DOD healthcare system, the only other one which has similar occupations outside of HHS and the VA, has not been sufficiently explored recently by NIH leadership. The hiring of non-physician clinical and technical personnel also remains problematic.

4.5 Focus Group participants noted that information about established CC services was not consistently provided to new Institute employees with duties that impact patient safety and quality of care at the CC. Only a minority of Institutes routinely send their employees through CC training. Additional mandatory training could be promoted to inform fellows and medical staff about the specific types of problems and events that need to be documented and raised to the PI, especially regarding unanticipated or adverse clinical events. Some participants in Focus Group sessions learned about CC practices, processes, and procedures from their colleagues during the Focus Group meetings. These are practices that are already in place but not widely known. An example was the availability of the stroke consult service at Suburban Hospital and how to swiftly transfer suspected stroke patients to that facility.

4.6 Non-tenure track staff feel that they are not valued to the same degree as tenured or tenure track staff. Resources and recognition at the CC, according to some Focus Group participants, is concentrated on tenured and tenure track staff. Since clinical care is largely provided by non-tenure track staff, Focus Group participants felt that the NIH does not sufficiently reward clinical excellence at the CC. Several Focus Group participants observed that staff clinicians are largely excluded from certain programs

administered by NIH OD. For example, the 2017 DDIR Innovation Awards Request for Applications limits eligibility to NIH Intramural Principal Investigators, which appears to exclude CC staff clinicians regardless of their experience or their innovation.

Recommendations:

4.1 The NIH Director and CC CEO should develop and fund both professional development and succession planning for all key positions and functions at the CC.

4.2 The CC CEO should undertake an assessment of the evolving human capital requirements of the CC and develop a plan to recruit and retain staff essential to the core mission of the CC.

4.3 The CC CEO should address at the highest levels in HHS and NIH the slow and unresponsive HR process since protracted vacancies in key positions at the CC can impact patient safety.

4.4 Since compensation impacts the ability of the CC to recruit and retain staff, the NIH Director should assess VA and DOD HR authorities, procedures, practices, and salary scales for physicians and non-physician clinical and technical personnel for applicability to the CC. If statutory language is necessary for NIH to leverage these authorities, procedures, practices, and salary scales, the NIH Director should consider including such language in the annual NIH budget submission to HHS.[18] The selection of a CC COO is likely to be a meaningful step in addressing HR issues at the hospital.

4.5 The CC CEO and Institute Directors should take steps to ensure that new employee and contractor orientation programs (for those who have some contact with the CC) are aligned to include essential information about the CC. A CC-specific orientation program should be mandatory for anyone who works in the CC.

4.6 The CC CEO should seek funding for and establish a mechanism to support and recognize non-tenure track staff (e.g., staff clinicians and nurse practitioners) for clinical excellence by providing awards and equivalent resources for training and professional development similar to that provided to tenured and tenure track staff.

[18] It may be that sufficient authorities, procedures, and salary scales for the CC could be achieved by an amendment or amendments to the Delegation Agreement between HHS and the U.S. Office of Personnel Management.

Theme 5—Clinical Center Facilities, Equipment, and Systems

Discussion:

5.1 Infrastructure and building maintenance emerged as a major concern to Focus Group participants because of their direct impact on critical services and functions at the CC.[19] For example, the CC's operating rooms (ORs), located off of the original Magnuson building, experience frequent and multiple water leaks, delaying procedures because of the need to relocate to other ORs. Similarly, the Department of Transfusion Medicine (DTM), Department of Laboratory Medicine (DLM), RADIS, Department of Positron Emission Tomography (PET) and DPM are in outdated facilities located in the older buildings (i.e., Magnuson building and ACRF).[20]

5.2 Focus Group participants noted that there is a need to invest in management information systems for support functions at the CC. For example, there is no system to track room usage at the CC. This makes it difficult to consistently ensure that proper steps are taken to make hospital rooms ready for the next patient. Currently, requests for room cleaning are done by telephone or word of mouth. This could present quality of care and patient safety problems if a room, which had been used for isolation, was not properly disinfected prior to use by the next patient.

5.3 Some Focus Group participants thought that enhanced investments in equipment and systems for housekeeping and infection control are needed at the CC. These participants noted that there is little redundancy in some critical equipment at the CC and that this could impact quality of care and patient safety. For example, the CC has only one UV robot used for OR and isolation room disinfection.

5.4 Equipment vulnerabilities at the CC are a major subject of concern to Focus Group participants. Due to funding shortfalls and deferred maintenance, a substantial amount of essential equipment at the CC is well beyond its useful life. Indeed, some equipment is so old that parts are no longer available and the CC's biomedical equipment technicians must cannibalize some devices in order to keep others operational. The nurse call system is but one example of many equipment vulnerabilities at the CC. The present nurse call system is no longer supported by the manufacturer and elements of the system must be cannibalized in order to keep other elements of it operational. Focus Group participants felt this is an unsustainable and dangerous problem facing the CC.

5.5. Since the Clinical Research Information System (CRIS) is a commercial off-the-shelf system designed for clinical care, it is not fully capable of supporting CC research process needs. As a result, some Institutes have purchased their own research systems (e.g., NIAID uses CRIMSON) or keep hard copy records (shadow charts) that are not in the electronic medical record and, therefore, not broadly available. As a result of this, clinical care providers often are unable to find protocol-specific information (other than orders) if there is a need to check on protocol-specific requirements, for example, for obtaining an MRI.

Participants observed that it is often difficult to retrieve pertinent clinical patient information, including discharge records, from the current medical record system.

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[19] Since the Red Team Report was issued, ORF has made several strategic hires to enhance its healthcare construction and maintenance capabilities. These important additions to ORF were largely unknown to Focus Group participants at the time of these sessions.

[20] NIH is taking steps to remediate these facility issues, including construction of a new facility for DTM (2J) and, once the new DTM facility is completed, plans to renovate the current facility (3T).

Recommendations:

5.1 The NIH Director and CC CEO should address immediate and urgent facility needs in operating rooms, DPM, DTM, DLM, PET and RADIS. These facilities should be renovated or rebuilt in such a way that they become models for research organizations and magnets for investigators and patients seeking to participate in the very best and most technically sophisticated medical interventions. The size, quality, and sophistication of CC facilities should be driven by the CC strategic plan discussed above.

5.2 The CC CEO should undertake a review of the management information system needs for support functions at the CC (e.g., housekeeping, patient safety, and professional development) and commit (or, if insufficient funds are available within the CC budget, seek) funding to address these needs.

5.3 The CC CEO should undertake a review of gaps in essential housekeeping equipment for the CC and commit (or, if insufficient funds are available within the CC budget, seek) funding to address the same.

5.4 The CC CEO should undertake a review of equipment vulnerabilities at the CC and commit (or, if insufficient funds are available within the CC budget, seek) funding to replace equipment substantially past its useful life and not reliably in a state of good repair. Such a review should include an assessment of the life-cycle replacement program and budget for equipment at the CC.

5.5 The CC CEO should undertake a review of CRIS to determine if this is the best information system to support the intramural program optimally in the coming years.

REPORT – POSTSCRIPT

Since the very first day of the CC Engagement Project, it has been clear to me that NIH and CC leadership have been serious about listening to staff who work in Building 10 and responding to their concerns. Indeed, their very willingness to embark on such an introspective, self-critical process is, it seems to me, an indication of the fundamental soundness of the institution. The project began nearly twelve months ago and during that time periodic briefings and updates were given to NIH leadership as well as to two NIH advisory committees. As a result, a number of concerns and challenges identified by Focus Group participants have been addressed or are in the process of being addressed. For example, meaningful progress has been made in improving information sharing at the CC, including quarterly morbidity and mortality conferences and quarterly town hall meetings, ORS has been replaced with an enhanced system called STARS, essential facilities are being repaired or are scheduled for repair, investments are planned for the Materials Management and Environmental Services Department (i.e., the housekeeping department), a process to improve succession planning is in the works, and an initiative to enhance support to investigators is underway. There has also been progress in establishing uniform core IRB procedures, instituting a system to better track research blood draws and research imaging, and improving CC telecommunications systems and procedures.

In one of the early Focus Groups, a participant who had been particularly vocal observed that even with the challenges facing the CC, it is a great hospital and if someone he loves was eligible for a protocol and needed to be hospitalized, he would want them to come the CC. He would want them to come to the CC because the staff are devoted to patients and the science is without peer. There is no other place in the world like the CC. This was a sentiment I heard expressed in one way or another in every Focus Group, countless side meetings and one-on-one discussions. The individuals who participated in the sessions or otherwise contributed to the Engagement Project are passionate about the CC and dedicated to providing the CC's patients with the highest quality care. The issues raised by Focus Group participants, now memorialized in this report, should be understood in this context. And after more than ten months of work on this project and listening to hundreds of people discuss their concerns and the very real challenges facing the CC, I can say without the slightest hesitation that if someone I love was eligible for a protocol and needed to be hospitalized, I would want them to come to the CC.

The message of this report is that the CC is a great research hospital; one that has made magnificent contributions to biomedical research while providing high quality patient care. But for this to continue, CC governance must be streamlined, processes must be improved, and additional investments must be made in clinical equipment and infrastructure. If the concerns and challenges identified in this report are addressed by NIH and CC leadership—as some already have been, there is literally no limit to what can be achieved at Building 10.

Stewart Simonson
Washington, DC

Clinical Center Engagement Working Group

Victoria Anderson, MSN, CRNP
Deputy Director for Clinical and Research Support Services,
Center for Interventional Oncology, CC

Gina Cobb-Martinez
Unit Clerk/Program Support Specialist, CC

Lisa Cordes, PharmD, BCACP, BCOP
Oncology Clinical Pharmacy Specialist, CC

Denise Ford MS, RD, PMP
Chief, Patient Relations and Recruitment Services, CC

Juan C. Gea-Banacloche, MD
Head, Infectious Diseases Unit, Experimental Transplantation and Immunology Branch, NCI
Chief, Infectious Diseases Consultation Service, NIAID

Christine Grady, MSN, PhD
Chief, Department of Bioethics, CC

Colleen Hadigan, MD, MPH
Staff Clinician, Laboratory of Immunoregulation, NIAID

Theo Heller, MD
Chief, Clinical Research Section - Translational Hepatology Unit,
Liver Diseases Branch, NIDDK

Chuong D. Hoang, MD
Surgeon & Tenure Track Investigator,
Thoracic and GI Oncology Branch, CCR, NCI

Melissa Hubbard, MSN, RN
Clinical Manager, CC

Deldelker James, MSN, RN, OCN, BMTCN
Clinical Manager, CC

Jennifer A. Kanakry, MD
Clinical Head of Transplant, Experimental Transplantation and Immunology Branch, NCI

Janice S. Lee DDS, MD, FACS
Clinical Director and Chief, Craniofacial Anomalies and Regeneration Section, NIDCR

Michail S. Lionakis, MD, ScD
Clinical Investigator and Chief, Fungal Pathogenesis Unit, Laboratory of Clinical Infectious Diseases, NIAID

Patricia Prince, M.ED, LICSW
Clinical Social Worker, CC

Anthony F. Suffredini, MD
Deputy Chief, Senior Investigator,
Critical Care Medicine Department, CC

Danielle Townsley, MD, MSc
Hematology Clinician, Hematology Branch,
Cell Biology Section, NHLBI

Laura Wake, MD
Hematopathology Fellow, NCI

Carlos A. Zarate, Jr., MD
Chief Experimental Therapeutics & Pathophysiology Branch & Section,
Neurobiology and Treatment of Mood Disorders, Division of Intramural Research Program, NIMH

Biographical Information for Stewart Simonson

Stewart Simonson is legal counsel and corporate secretary of The CRUDEM Foundation, Inc., a New Jersey-based non-profit corporation whose sole mission is to oversee and support Hôpital Sacré-Coeur de Milot, a 200-bed definitive care hospital and public health provider in northern Haiti. Simonson spends about half his time in Milot as resident advisor to the hospital. His duties include legal affairs, compliance, strategic planning, fundraising, government relations, and board support.

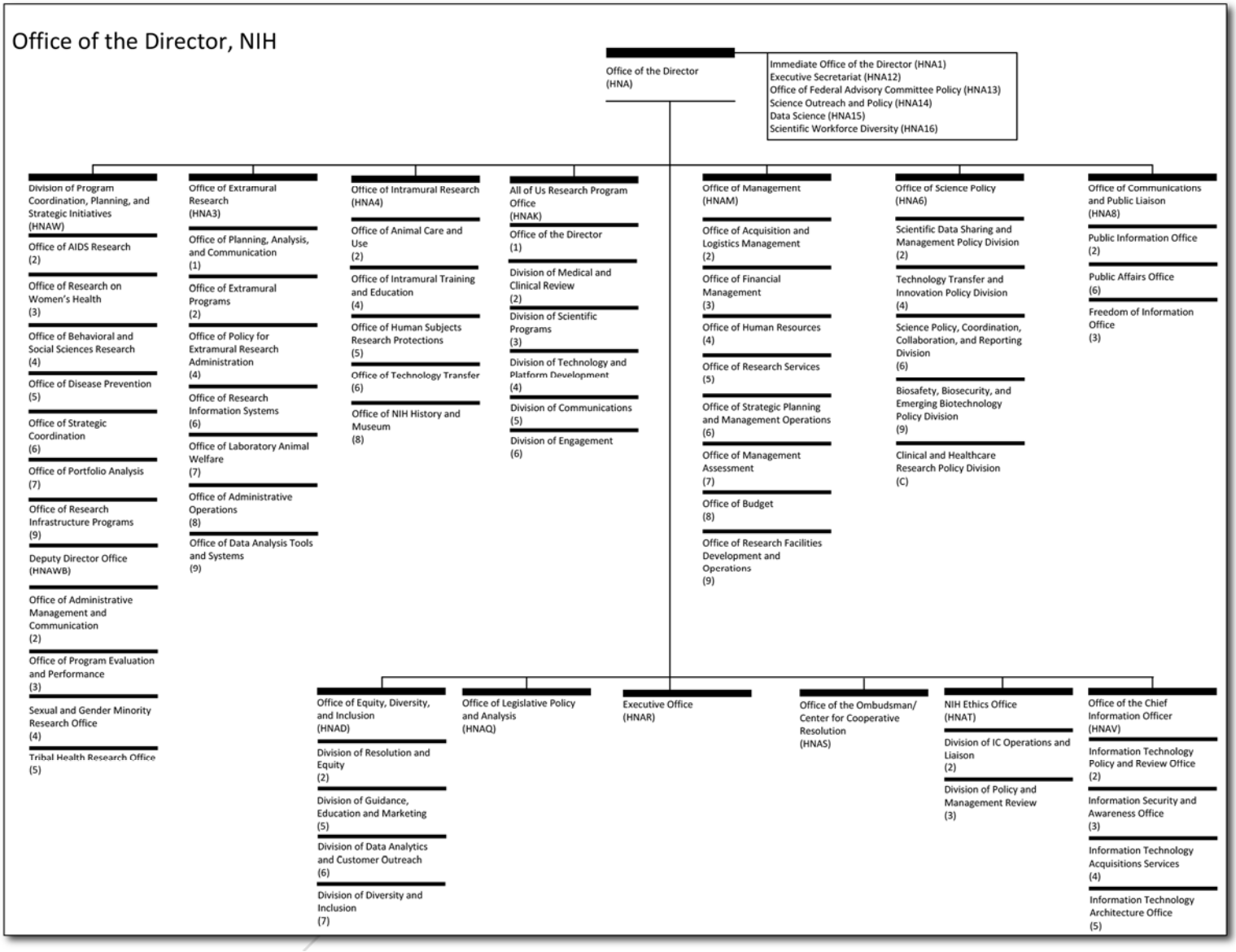
Before his work in Haiti, Simonson was senior vice president and general counsel for GRM Futures Group, an international development firm with projects in some 20 countries.

Prior to joining GRM Futures Group, Simonson was vice president for government affairs at SRA International, Inc., a professional services consulting firm. He was previously SRA's vice president and director of strategic initiatives within the Global Health business.

Simonson spent nearly five years with the U.S. Department of Health and Human Services, where he served in several senior positions, including Deputy General Counsel and Assistant Secretary for Public Health Emergency Preparedness. As Assistant Secretary, Simonson coordinated public health preparedness activities of the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health. He was instrumental in drafting and securing passage of the Project BioShield Act of 2004. From his first days at the Department of Health and Human Services, Simonson played a strong role in improving pandemic influenza preparedness and served as the Secretary's point person for this work. Simonson was integrally involved in the development of the Special Clinical Studies Unit at the NIH Clinical Center.

Simonson has received several awards recognizing his contributions to public health, including the Surgeon General's Medallion and the Food and Drug Administration Center for Biologics Evaluation and Research's Public Health Achievement Award.

Earlier in his career, Simonson was corporate secretary at the National Railroad Passenger Corporation (Amtrak) and chief legal counsel to the governor of Wisconsin.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Office of Research on Women's Health (3)
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Office of Program Evaluation and Performance (3)
Sexual and Gender Minority Research Office (4)
Tribal Health Research Office (5)
Office of Extramural Research (HNA3)
Office of Planning, Analysis, and Communication (1)
Office of Extramural Programs (2)
Office of Policy for Extramural Research Administration (4)
Office of Research Information Systems (6)
Office of Laboratory Animal Welfare (7)
Office of Administrative Operations (8)
Office of Data Analysis Tools and Systems (9)
Office of Intramural Research (HNA4)
Office of Animal Care and Use (2)
Office of Intramural Training and Education (4)
Office of Human Subjects Research Protections (5)
Office of Technology Transfer (6)
Office of NIH History and Museum (8)
All of Us Research Program Office (HNAK)
Office of the Director (1)
Division of Medical and Clinical Review (2)
Division of Scientific Programs (3)
Division of Technology and Platform Development (4)
Division of Communications (5)
Division of Engagement (6)
Office of Management (HNAM)
Office of Acquisition and Logistics Management (2)
Office of Financial Management (3)
Office of Human Resources (4)
Office of Research Services (5)
Office of Strategic Planning and Management Operations (6)
Office of Management Assessment (7)
Office of Budget (8)
Office of Research Facilities Development and Operations (9)
Office of Science Policy (HNA6)
Scientific Data Sharing and Management Policy Division (2)
Technology Transfer and Innovation Policy Division (4)
Science Policy, Coordination, Collaboration, and Reporting Division (6)
Biosafety, Biosecurity, and Emerging Biotechnology Policy Division (9)
Clinical and Healthcare Research Policy Division (C)
Office of Communications and Public Liaison (HNA8)
Public Information Office (2)
Public Affairs Office (6)
Freedom of Information Office (3)
Office of Equity, Diversity, and Inclusion (HNAD)
Division of Resolution and Equity (2)
Division of Guidance, Education and Marketing (5)
Division of Data Analytics and Customer Outreach (6)
Division of Diversity and Inclusion (7)
Office of Legislative Policy and Analysis (HNAQ)
Executive Office (HNAR)
Office of the Ombudsman/ Center for Cooperative Resolution (HNAS)
NIH Ethics Office (HNAT)
Division of IC Operations and Liaison (2)
Division of Policy and Management Review (3)
Office of the Chief Information Officer (HNAV)
Information Technology Policy and Review Office (2)
Information Security and Awareness Office (3)
Information Technology Acquisitions Services (4)
Information Technology Architecture Office (5)

Recommendations

Theme 1: Governance, Administration and Accountability

1.1 The NIH Director, the CC CEO[21], the CC Chief Scientific Officer (CSO), and Institute Directors should jointly develop a multi-year strategic plan for the CC that addresses the following:

- An organizational structure for the CC that empowers the CC CEO to manage the hospital with clear lines of authority and accountability;
- Human capital development and retention at the CC;
- Infrastructure and equipment needs of the CC;
- Metrics of success for the CC, including optimal inpatient and outpatient census, research productivity, patient safety, training, and compliance with applicable regulatory requirements;
- Metrics of success for inpatient and outpatient clinical services and departments at the CC; and,
- Metrics of success for Institute clinical research programs at the CC.

The strategic plan should include specific funding commitments from NIH OD and the Institutes aligned with the above.
Proposed Responsible Official: NIH Director

1.2 Institute Directors should delegate to the CC CEO authority over Institute personnel and activity at the CC impacting quality of care and patient safety.
Proposed Responsible Official: NIH Director

1.3 The NIH Director should grant authority to the CC CEO to set ORF priorities for the CC as well as authority to hold ORF accountable for the quality and timeliness of work undertaken at the CC.
Proposed Responsible Official: NIH Director

1.4 The NIH Director should obtain from the CC CEO an annual written assessment on the CC-related performance of the NIH Deputy Director for Intramural Research and the NIH Deputy Director for Management and provide same to the NIH Principal Deputy Director, who is responsible for annually reviewing these two positions.
Proposed Responsible Official: NIH Director

1.5 The CC CEO should develop uniform admission and discharge procedures and basic documentation requirements for all CC patients.
Proposed Responsible Official: CC CEO

1.6 The CC CEO should be empowered by the NIH Director and Institute Directors to hold all staff who work in the CC accountable for meeting minimum standards of documentation in the medical record that have been established for the CC by the CC CEO. Medical records should then be monitored regularly to assure completeness and accuracy.
Proposed Responsible Official: NIH Director

[21] The position of CC CEO was created in mid-2016 to replace the discontinued position of CC Director. James Gilman, MD, was selected as the first CC CEO in December 2016.

1.7 In the annual performance evaluation of each Institute Director with responsibility for research at the CC, the NIH Director should include an assessment of such Institute's CC program, including patient safety and quality of patient care, inpatient and outpatient activity, and quality and extent of services provided at the CC, each informed by a written assessment by the CC CEO.
Proposed Responsible Official: NIH Director

1.8 The CC CEO should propose revisions in the membership and bylaws of the MEC to ensure better representation of staff with expertise in clinical care at the CC (e.g., staff clinicians) to balance the expertise in research now present among members of the MEC.
Proposed Responsible Official: CC CEO

1.9 The CC CEO should review the scope of authority set forth in the bylaws of the MEC as well as its practices and procedures to ensure that the MEC is properly constituted, organized, and managed to meet the needs of the CC, including patient safety and quality of care requirements.
Proposed Responsible Official: CC CEO

1.10 The CC CEO should review the credentialing process at the CC to ensure medical staff are authorized to perform only those procedures in which they have appropriate training, experience and demonstrated proficiency.
Proposed Responsible Official: CC CEO

1.11 The NIH Director should require that each Institute Director with responsibility for research at the CC, along with the Scientific Director for such Institute, to go on clinical rounds with their respective CC staff at least once per quarter.
Proposed Responsible Official: NIH Director

1.12 To the extent consistent with the multi-year strategic plan discussed in 1.1 above, the NIH Director and Institute Directors should delegate authority to the CC CEO for clinical, administrative, and operational activity (personnel, space, facility management and maintenance, facility construction, equipment acquisition and maintenance) that occurs within the clinical areas of the Building 10 complex whether such activity is performed by Institute staff or NIH OD staff.
Proposed Responsible Official: NIH Director

1.13 The CC CEO should be empowered by the NIH Director and Institute Directors to hold Institute leadership and staff who work in the CC accountable for inpatient and outpatient services, including timely on-call responsiveness and availability.
Proposed Responsible Official: NIH Director

1.14 The NIH Deputy Director for Intramural Research should establish uniformity in core IRB procedures and policies.
Proposed Responsible Official: NIH Deputy Director for Intramural Research

1.15 The CC CEO should consider moving DPM and Interventional Radiology nurses to the CCND.
Proposed Responsible Official: CC CEO

Theme 2: Quality of Care and Clinical Research

2.1 The CC CEO should seek funding to enhance services provided by Institutes, such as hospitalists with categorical expertise in the areas they would be covering. Such hospitalists might include those with expertise in general pediatrics, pediatric anesthesia, pediatric critical care, or multi-institute clinical programs such as that for stem cell transplantation. The objective of this funding should be to ensure the quality of inpatient, outpatient, and consultative services at the CC. Formal surveys and targeted operations reviews should also be considered as means of evaluating quality of care, patient safety, and support for research and training for American Council of Graduate Medical Education (ACGME) fellows.
Proposed Responsible Official: CC CEO

2.2 The NIH Director should commit funding for additional and uniform support to clinical researchers across the CC (e.g., for investigator training, protocol navigators, medical writers, study coordinators, data management/statistical support) as well as to utilize independent monitors for protocols to ensure objective reporting and regulatory compliance.
Proposed Responsible Official: NIH Director

2.3 The CC CEO should develop a CC-wide process for dealing with differences in opinion between staff when patient management issues conflict or do not align with research objectives. Best practices currently employed some Institutes for addressing these differences of opinion should be considered by the CC CEO in developing the recommended CC-wide process.
Proposed Responsible Official: CC CEO

2.4 The CC CEO should develop mechanisms to provide appropriate expertise for the conduct of high-risk, low-volume procedures at the CC. This may require obtaining specialty consultation or intervention support from outside the CC (e.g., Walter Reed National Military Medical Center, Children's National Medical Center).
Proposed Responsible Official: CC CEO

2.5 The CC CEO should develop and implement a system to better track the frequency and volume of research blood draws and imaging tests, especially for patients in multiple protocols and healthy volunteers to assure that established limits for research blood volume and radiation exposure guidelines are not exceeded.
Proposed Responsible Official: CC CEO

2.6 The CC CEO should harmonize CC policies and procedures applicable to all CC functions whether performed by CC, NIH OD, or Institute staff.
Proposed Responsible Official: CC CEO

2.7 The CC CEO should require that training on CC clinical policies, procedures, and quality of care and patient safety matter be provided annually to all those involved in clinical care, and that compliance with such requirements be tracked by supervisory staff.
Proposed Responsible Official: CC CEO

2.8 The CC CEO should provide (or, if insufficient funds are available within the CC budget, seek) funding for CC access to an electronic centralized learning system in order to help staff stay current on clinical care developments and ensure compliance with mandatory requirements.
Proposed Responsible Official: CC CEO

2.9 The CC CEO should provide (or, if insufficient funds are available within the CC budget, seek) funding to reduce dependence on per diem and contract nurses who are not familiar with CC policies and procedures, especially in high risk areas such as critical care, oncology, and services which provide stem cell therapies. The CEO should also identify best practices among institutes for protocol briefings for nursing staff and consider adopting a CC-wide policy on protocol briefings based on these best practices.
Proposed Responsible Official: CC CEO

2.10 The CC CEO should develop mechanisms to reliably and at short notice use outside providers to address gaps in clinical services that cannot readily be filled by intramural resources. Such mechanisms might include Interagency Agreements with the Department of Defense (DOD) and Department of Veterans Affairs (VA), or contracts with Suburban Hospital, Children's National Medical Center, and other area healthcare facilities. These mechanisms should be designed to reliably provide the CC with needed clinical services on a 24/7 basis.
Proposed Responsible Official: CC CEO

2.11 The CC CEO should develop guidelines for all staff who practice at the CC, including Institute staff, on circumstances in which the prevailing standards of care apply and circumstances in which such standards of care do not apply. All staff should be trained in the guidelines and held accountable for compliance with them. The CC CEO should also make didactic and training opportunities available to staff to maintain their knowledge and experience in practicing standards of care. The selection of a Chief Medical Officer for the CC is likely to be a meaningful step in addressing confusion concerning applicability of prevailing standards of care at the hospital.
Proposed Responsible Official: CC CEO

2.12 The NIH Director and CC CEO should establish procedures to ensure that ambulances coming to the NIH for emergency transfers from the CC are expedited through campus perimeter security.
Proposed Responsible Official: NIH Director

2.13 The CC Chief Nursing Officer (CNO) should appoint a sufficient number of transport nurses certified in ACLS and PALS to facilitate and accompany 24/7 emergency transfers from the CC that utilize the NIH Fire Department's BLS ambulance.
Proposed Responsible Official: CC CNO

2.14 The CC CNO, with the support of the CC CEO, should seek *Magnet* recognition from the American Nurse Credentialing Center (ANCC) for the CC. *Magnet* recognition would help to validate the CC's commitment to quality of care and patient safety. *Magnet* recognition would likely be useful in recruiting and retaining CC nurses.
Proposed Responsible Official: CC CNO

2.15 The CC CEO should improve administrative support for patient care services to enable floor nurses to focus more of their time on patient care (e.g., sufficient support staff should be available so that floor nurses do not need to leave their patient care duties to carry out administrative activities).
Proposed Responsible Official: CC CEO

2.16 The CC CEO should consider providing small group educational sessions on event reporting (e.g., reporting of unanticipated problems, protocol deviations, and non-compliance at the NIH).
Proposed Responsible Official: CC CEO

2.17 The CC CEO should consider creating communities of practice at the CC (e.g., pediatricians, cardiologists, surgeons, internists, psychiatrists, CRNPs, CRNAs) to provide a greater degree of cohesion and professional support for staff who work in these specialties.
Proposed Responsible Official: CC CEO

2.18 The CC CEO should undertake a review of policies and procedures related to the movement of specimens at the CC to ensure such policies and procedures are appropriate and effective. The CC CEO should hold all staff (whether employed by the CC or Institutes) accountable for following existing or revised policies and procedures related to the movement of specimens at the CC.
Proposed Responsible Official: CC CEO

Theme 3: Communications and Engagement

3.1 The CC CEO should consult with a cross section of staff who work in the CC (whether employed by the CC, Institutes, or NIH OD) to develop a comprehensive communications plan for intramural staff involved in patient care at the CC. The objective of this plan should be to improve the quality and accessibility of information shared with staff in Building 10.
Proposed Responsible Official: CC CEO

3.2 The CC CEO should increase the frequency and staff awareness of morbidity and mortality review conferences at the CC; improve reporting to staff about the disposition of misadventure and unexpected events at the CC; require annual training of staff on CC policies, procedures and services (e.g., stroke consult service); and develop a communications algorithm or other mechanism to ensure that CC staff learn about important events and occurrences directly from NIH or CC leadership.
Proposed Responsible Official: CC CEO

3.3 The CC CEO should establish quarterly Town Hall meetings and establish an ongoing focus group/engagement process.
Proposed Responsible Official: CC CEO

3.4 The CC CEO should ensure that feedback is readily available to all those who make submissions to the ORS (now STARS)
Proposed Responsible Official: CC CEO

3.5 The CC CEO should commit (or, if insufficient funds are available within the CC budget, seek) funding and ensure accountability for unified telecommunications systems, policies, and processes for all patient care staff working at the CC.
Proposed Responsible Official: CC CEO

3.6 NIH OD and the CC should develop a proactive strategy to communicate CC improvements and success stories (historical, recent, and current) to NIH staff and external stakeholders using electronic methods such as websites and email as well as physical displays in public areas of the hospital.
Proposed Responsible Official: NIH Director

Theme 4: Organizational Development and Human Resources

4.1 The NIH Director and CC CEO should develop and fund both professional development and succession planning for all key positions and functions at the CC.
Proposed Responsible Official: NIH Director

4.2 The CC CEO should undertake an assessment of the evolving human capital requirements of the CC and develop a plan to recruit and retain staff essential to the core mission of the CC.
Proposed Responsible Official: CC CEO

4.3 The CC CEO should address at the highest levels in HHS and NIH the slow and unresponsive HR process since protracted vacancies in key positions at the CC can impact patient safety.
Proposed Responsible Official: CC CEO

4.4 Since compensation does impact the ability of the CC to recruit and retain staff, to the extent it does not presently occur, the NIH Director should assess VA and DOD HR authorities, procedures, practices, and salary scales for physicians and non-physician clinical and technical personnel for their applicability to the CC. If statutory language is necessary for NIH to leverage these authorities, procedures, practices, and salary scales, the NIH Director should include such language in the annual NIH budget submission to HHS. The selection of a CC COO is likely to be a meaningful step in addressing HR issues at the hospital.
Proposed Responsible Official: NIH Director

4.5 The CC CEO and Institute Directors should take steps to ensure that new employee and contractor orientation programs (for those who have some contact with the CC) are aligned to include essential information about the CC. A CC-specific orientation program should be mandatory for anyone who works in the CC.
Proposed Responsible Official: CC CEO

4.6 The CC CEO should seek funding for and establish a mechanism to support and recognize non-tenure track staff (e.g., staff clinicians and nurse practitioners) for clinical excellence by providing awards and equivalent resources for training and professional development similar to that provided to tenured and tenure-track staff.
Proposed Responsible Official: CC CEO

Theme 5: Clinical Center Facilities, Equipment and Systems

5.1 The NIH Director and CC CEO should address immediate and urgent facility needs in operating rooms, DPM, DTM and DLM. These facilities should be renovated or rebuilt in such a way that they become models for research organizations and magnets for investigators and patients seeking to participate in the very best and most technically sophisticated medical interventions. The size, quality, and sophistication of CC facilities should be driven by the CC strategic plan discussed above.
Proposed Responsible Official: NIH Director

5.2 The CC CEO should undertake a review of the management information system needs for support functions at the CC (e.g., housekeeping, patient safety, and professional development) and commit (or, if insufficient funds are available within the CC budget, seek) funding to address these needs.
Proposed Responsible Official: CC CEO

5.3 The CC CEO should undertake a review of gaps in essential housekeeping equipment for the CC and commit (or, if insufficient funds are available within the CC budget, seek) funding to address the same.

Proposed Responsible Official: CC CEO

5.4 The CC CEO should undertake a review of equipment vulnerabilities at the CC and commit (or, if insufficient funds are available within the CC budget, seek) funding to replace equipment substantially past its useful life and not reliably in a state of good repair. Such a review should include an assessment of the life-cycle replacement program and budget for equipment at the CC.
Proposed Responsible Official: CC CEO

5.5 The CC CEO should undertake a review of CRIS to determine if this is the best information system to support the intramural program optimally in the coming years.
Proposed Responsible Official: CC CEO