Message from the Clinical Center Director

Our nurses say, “There’s no other hospital like the NIH Clinical Center.” Our record of advancing medical discovery, inspiring and mentoring future generations of outstanding investigators in a broad range of specialties, and our ceaseless commitment to patients—partners in our research—are unparalleled. In the pages that follow, I’m pleased to outline our roadmap for building on this success in 2016, and to share a few highlights.

The year ahead holds extraordinary promise with the implementation of President Obama’s precision medicine initiative. With NIH ushering in this exciting new era of medicine, and as the largest hospital in the world devoted totally to research, the Clinical Center is poised to contribute, especially in complementing genome-based phenotype discoveries related to this initiative.

Health officials and experts from around the globe visit the Clinical Center to witness such cutting edge research performed by our Institute colleagues, but they also find themselves marveling at our unique patient-centric environment. This is most profoundly evidenced in our patient safety initiatives. Clinical research is inherently risky, and in 2016, I am pledging to re-double our commitment to patient safety, with a slate of new and enhanced initiatives, including adopting a state-of-the-art patient call system, enhanced reporting and feedback systems, and organization-wide learning programs.

Further, our world-renowned programs to train the top researchers of tomorrow will continue to expand and diversify. This ensures that the future of medical discovery is bright not just for 2016, but for decades to come.

The Clinical Center looks forward with optimism, tireless dedication, and careful planning. We know that biomedical research is an intense, dynamic, and complex enterprise. The Clinical Center embraces the challenge while standing on our pillars of world class training, patient care, and research practices, and anchored by our patient-centric values and belief in the vast, ever-growing potential of both science and the individual.

Thank you for taking the time to familiarize yourself with our 2016 operating plan. I genuinely welcome your thoughts and feedback.

John I. Gallin, M.D.
Director, NIH Clinical Center
Planning Framework

[Graphic: Planning Framework]

This is a circular graphic that depicts the Clinical Center planning framework, which represents a continuous improvement model. The outside circle encompasses Environmental Influences, including Internal & External Stakeholder Input, Key Influencing Factors, and Governance & Advisory Groups depicted as a continuous loop.

The interior circle reflects the strategic components of the plan, including Vision & Mission, Guiding Principles, and Long Term Goals. The vision and mission feed into the core processes which then inform the long term goals.

The middle circle represents the operational components of the plan, and has at its heart the targets. The targets are encircled by a plan-do-check-act cycle.

Planning/Budget Review Process

[Chart: Planning/Budget Review Process]

October
- Institute Research Plans Submitted to Clinical Center (this is a programmatic requirement)

November
- Clinical Center Identifies Priorities for Hospital Infrastructure and Institute Support (programmatic requirement)

December
- Scientific & Clinical Directors Provide Input on Program Requirements and Preliminary Budget (programmatic requirement)

January
- Clinical Center Develops Draft Budget (programmatic requirement)

February
- Institute Leadership Provides Input on Draft Budget (programmatic requirement)

March/April
- NIH Advisory Board for Clinical Research (budget review)

May
- NIH Clinical Center Governing Board (budget review)

June/July
- NIH Steering Committee (budget review)

August
- IC Directors (budget review)
Vision Statement

A vision statement answers the question: “What do we strive to be?” and is a shared view that defines what the organization wants to do or become.

As America’s research hospital, we will lead the global effort in training today’s investigators and discovering tomorrow’s cures.

Mission Statement

A mission statement answers the question: “What is our fundamental purpose?”

The NIH Clinical Center provides a model environment for:
- clinical research
- patient care and safety
- training

Guiding Principles

Guiding principles are the values underpinning the activities undertaken by an organization.

Respect for the Individual
At the heart of the NIH Clinical Center mission is a deep and abiding respect for the rights, preferences, and values of the individuals and communities we serve.

Innovation
The NIH Clinical Center encourages and promotes innovative practices in clinical research, patient care, training, and operations.

Diversity and Inclusion
By bringing diverse individuals together, the NIH Clinical Center addresses the issues facing the global community of patients and staff while promoting an inclusive environment.

Dissemination of Information
The NIH Clinical Center fosters global communication to disseminate innovations.

Judicious Use of Resources
Through efficient practices, the NIH Clinical Center maximizes resources dedicated to clinical research and patient care.
Long Term Goals: 2014-2018

Long term goals translate the vision, mission and guiding principles into performance-based action plans intended for the next five years.

Clinical Research
Realize the NIH clinical research vision for precision medicine including such techniques as comprehensive phenotyping and genomics, pediatrics, emerging infectious diseases, clinical neurosciences, and translational therapeutics such as cell therapy, vector development, and immunologic interventions.

Patient Care and Safety
Provide outstanding clinical care and strengthen the culture of patient safety by minimizing adverse events, engaging patients, and leveraging health information technology.

Training
Maintain a robust and diverse training program that employs emerging technologies to deliver innovative training in clinical research, patient safety, and service excellence.

2016/2017 Targets

Core Process: Clinical Research
Long Term Goal: Realize the NIH clinical research vision for precision medicine including such techniques as comprehensive phenotyping and genomics, pediatrics, emerging infectious diseases, clinical neurosciences, and translational therapeutics such as cell therapy, vector development, and immunologic interventions.
Targets:
- Implement Pharmacy remediation plan
- Activate new cell processing facility, new cGMP for PET research, and new Radiopharmacy
- Support genome-based phenotype discovery

Core Process: Patient Care and Safety
Long Term Goal: Provide outstanding clinical care and strengthen the culture of patient safety by minimizing adverse events, engaging patients, and leveraging health information technology.
Targets:
- Complete regulatory-required renovations to MRI and blood donor areas
- Enhance culture of patient safety through augmented training and improved occurrence reporting
- Replace patient call system
- Strengthen pediatric infrastructure
- Increase OR capacity
- Activate referring physician portal
Core Process: Training
Long Term Goal: Maintain a robust and diverse training program that employs emerging technologies to deliver innovative training in clinical research, patient safety, and service excellence.
Targets:
• Develop Medical Scientist Training Program clinical research elective
• Expand research training opportunities to minority-serving institutions
• Expand patient care and safety simulation training

Operational Efficiencies/Cost Savings:
• Evaluate the model of care in the clinics with a goal of achieving cost savings through new management controls and staffing changes
• Develop prospective process to assess impact of IC hires on hospital costs
• Implement centralized appointment scheduling system
• Implement strategies to reduce costs for take home drugs

Financial Assessment of 2016/2017 Targets
[Chart: Financial Assessment of 2016/2017 Targets]

Clinical Research
Target 1: Implement Pharmacy remediation plan
Funding Estimate: $1.9M

Target 2: Activate new cell processing facility, new cGMP for PET research and new Radiopharmacy
Funding Estimate: $1.5M

Target 3: Support genome-based phenotype discovery
Funding Estimate: Existing resources for current scope

Patient Care and Safety
Target 1: Complete regulatory-required renovations to MRI and blood donor areas
Funding Estimate: Funded in FY16 budget

Target 2: Enhance culture of patient safety through augmented training and improved occurrence reporting
Funded Estimate: $0.6M

Target 3: Replace patient call system
Funding Estimate: $4.0M

Target 4: Strengthen pediatric infrastructure
Funding Estimate: $2.0M

Target 5: Increase OR capacity
Funding Estimate: $1.2M

Target 6: Activate referring physician portal
Funding Estimate: Prior year funding
Training
Target 1: Develop Medical Scientist Training Program clinical research elective
Funding Estimate: Existing resources

Target 2: Expand research training opportunities to minority-serving institutions
Funding Estimate: Existing resources

Target 3: Expand patient care and safety simulation training
Funding Estimate: Existing resources

Other Operational Initiatives

[Chart: Other Operational Initiatives]

In addition to the 2016/2017 Targets, the Clinical Center has plans to pursue a number of important operational initiatives not included in this plan. All initiatives, whether or not included as priorities in this plan, are evaluated regularly and adjustments are made to the Clinical Center’s portfolio of activities to ensure that adequate resources are allocated to continue important baseline activities as well as targets.

Clinical Research Support

Traumatic Brain Injury/Post Traumatic Stress Disorder collaboration
Comments: Provide leadership, clinical assistance and clinical research support for this joint initiative with Walter Reed National Military Medical Center

Translational Research in Pediatrics Program (TRIPP)
Comments: Collaboration with Children’s National Medical Center

NIH/FDA Center for Drug Evaluation and Research (CDER) collaboration
Comments: Training and ready access to FDA staff for clinical investigators planning IND applications and wishing to schedule pre-IND meetings for consultation

Evaluate clinical protocol metrics related to INDs
Comments: Collaborating with IC Clinical Directors to implement annual surveys regarding initial IND application submitted to FDA by Intramural Program Investigators

Patient Safety/Clinical Care

Clinical Research Nursing-setting the leadership agenda
Comments: The Nursing Department is expanding its work on advancing clinical research as a nursing subspecialty to include development of core metrics and defining the role of leadership in a clinical research environment

Management of the hospital environment to prevent outbreaks of multidrug-resistant organisms
Comments: The Clinical Center is continuing to monitor existing and new organisms
Clinical Dashboards
Comments: Consolidate and automate collection and analysis of clinical quality and patient safety performance data

Refine strategies for routine and after-hours campus access for patients
Comments: Implement monthly ‘Did You Know’ messaging to Clinical Center and IC staff to assure consistent communications to patients and patient visitors. Pursue continuous improvements to existing strategies as issues arise and feedback is received

Training

Core Clinical Research Curriculum
Comments: Annual courses, “Introduction to the Principles and Practice of Clinical Research,” “Principles of Clinical Pharmacology,” and “Ethical and Regulatory Aspect of Clinical Research” are offered to a broad range of domestic and internal partners

Medical Research Scholars Program (MRSP)
Comments: Ongoing program for medical, dental, and veterinary students; expanding outreach to minorities and pursuing sustained public and private funding for program

Clinical Electives Program for visiting medical/dental students
Comments: Exposing senior medical or dental students from US or international schools to a variety of short-term clinical specialty/subspecialty rotations designed to facilitate engagement in the practice of translational medicine and to enhance understanding of the design and implementation of human subject research protocols

Assessment of training program alumni productivity
Comments: Determining metrics of success and program output for alumni of NIH clinical and research training programs (CRTP, MRSP, GME, and NIH Duke Training Program in Clinical Research)

Sabbatical in Clinical Research Management
Comments: Enhancing clinical research management skills for mid-career professionals

Clinical and Translational Research Course for Ph.D. students
Comments: Expose young basic scientists currently enrolled in doctoral programs to the collaborative nature of clinical and “bench-to-bedside” research and NIH Ph.D. role models in order to increase awareness of career options in clinical and translational research for Ph.D. scientists and to stimulate research partnerships

Information Technology

Clinical Research Information Systems (Sunrise Clinical Manager/SCM) upgrade
Comments: Required upgrade of the system to version 15.3 CU 3. As part of the upgrade the system will provide a mirrored system to aid in the business continuity of the system

Display clinical genomics within the Clinical Research Information System
Comments: Work with NHGRI and NCI to develop a mechanism to display genomics and clinical data in an integrated format to Clinical Research Information System users
Rollout two-factor authentication to inpatient units and outpatient clinics, and areas with shared workstations including Radiology, Laboratory Medicine, and Perioperative Medicine
Comments: Mandated Workstation on Wheels (WOW), shared computer, Apple two-factor implementation: March 2016

Clinical Center unified communications
Comments: As part of NIH-wide initiative, replacement of existing phone technology to Voice over Internet Protocol (VOIP), to achieve significant cost savings and provide enhanced communication capabilities

Migrate the patient portal to a patient health record
Comments: Through a patient health record, patients will be able to link health data from multiple organizations into one view to enable users to manage medical data in one place

Integrate pharmacogenomics into the Clinical Research Information System
Comments: The system will automatically order exome sequencing based on specific approved medications, utilizing this data to enable clinical decision support for providers in the Clinical Research Information System

IT Disaster Recovery (Phase I)
Comments: To meet Federal Information Security Management Act requirements, the Clinical Center will develop a business case and implementation plan for a Disaster Recovery site outside of the current datacenter

Capital Equipment/Facilities

Major renovation of Clinical Center departments located in Ambulatory Care Research Facility (ACRF)
Comments: Includes imaging, OR’s, transfusion medicine, laboratory medicine, and PET. The Clinical Center is working with NIH leadership to secure funding

Establish Facility Life Cycle Replacement Plan and funding
Comments: A systematic, multiyear refurbishment cycle is underway to improve the appearance of areas (units, clinics, public spaces) throughout the Clinical Center, with priority given to those impacting patient safety; an annual budget for refurbishment has been established, using hospital benchmarks for replacement cycles

Wayfinding Using Mobile Devices
Comments: Pursuing additional application capabilities to enhance wayfinding using mobile devices within the Clinical Center complex; vendor was selected, implementation has been taking place, full rollout will occur in 2016

Renovate patient care unit waiting rooms
Comments: Continue to partner with Friends of Patients at the NIH for funding to enhance these amenities
**Business Processes**

Protocol resource impact assessment automation through implementation of workflow documentation tool
Comments: To improve the efficiency of the Protocol Resource Impact Assessment (PRIA) form through implementation of an automated workflow tool; based on success of implementation; the tool may be applied to other processes such as Memorandums of Understanding and Interagency Agreements

Financial modeling for predictive resource planning
Comments: To enable the Clinical Center to simulate the annual cost impacts of new protocols based on key protocol metrics

**Workforce**

Clinical Center employee survey
Comments: Assess employee satisfaction in areas such as career development, management, work environment, employee engagement, and diversity

Comprehensive workforce data review by Clinical Center departments
Comments: Conduct department-level workforce analysis and planning based on compensation and award history, turnover, retirement eligibility, diversity, and employee survey data including onboarding and separation surveys

Project SEARCH
Comments: Identify new sites for placement of interns with intellectual disabilities

**Measuring Success**

[Graphic: Operational Metrics]

The Balanced Scorecard\(^1\) approach below illustrates the operational metrics used by the Clinical Center to evaluate performance which are monitored and reported throughout the year.

**Operational Metrics**

- **Clinical Care and Patient Safety**
  - Patient Activity
    - Inpatient Days
    - Outpatient Visits
  - Clinical quality
    - Wait Times
    - Patient Falls
    - Hand Hygiene
    - Medication Errors
  - Patient perception
    - Ongoing Surveys

- **Operational Management**
• Cost Per Adjusted Patient Day
• CC Department Metrics

Clinical Research
• Protocol Activity
  o Active Protocols
  o Protocols by Type
• Clinical Activity
  o Hospital Census
  o Department Workload Indicators
• Training
  o Clinical Research Curriculum Participants
• Outside Collaborations
  o Applications and Awards
    ▪ Bench-to-Bedside Program
    ▪ U01 Program

Workforce
• Staffing
  o FTE and Contract Utilization
  o Turnover
  o Recruitments/Departures
• Accountability/Performance Management
  o Awards
  o Compensation
• Leadership Development
  o Curriculum Participation
  o Competency/Mandatory Training Compliance
• Diversity
  o Underrepresented Minorities

1 Developed in accordance with the Kaplan and Norton Balanced Scorecard Method. 