



Department of Clinical Research Informatics (DCRI)

Operational Review

April 1 & 2, 2014

Table of Contents

Section 1	Operational Review Background <ul style="list-style-type: none">• Operational Review Agenda• Operational Review Process & Charge• Operational Review Team Roster• Biographical Sketches	Page 7
Section 2	DCRI Overview <ul style="list-style-type: none">• Organizational Structure• Organizational Charts• Section Descriptions	Page 17
Section 3	Clinical Research Information System (CRIS) <ul style="list-style-type: none">• Departmental Ancillary Systems• Electronic Health Record (EHR) Background• HIMSS Analytics EMR Adoption Model• Meaningful Use	Page 29
	Research Support <ul style="list-style-type: none">• CRIS/Sunrise Acute Care• Other Systems/Departments that Support Research• IT Leadership Philosophy /Challenges	Page 47
Section 4	IT Leadership Philosophy/Challenges <ul style="list-style-type: none">• The “CIO Story”• DCRI Guiding Principles• Changing the Internal DCRI Culture• Applying The Leadership Philosophy: The Implementation of the NAS CC Fileserve• Moving Forward: Additional Refinement to the DCRI Methodology• IT Leadership Challenges• Customer Service Improvements• Resource Challenges/Project Requirements• Organizational Expectations• Maintaining Service Across Departments: Service Level Agreements	Page 51
	Staffing <ul style="list-style-type: none">• Staffing Model Analysis• Staffing Metrics• Staff Resumes of DCRI Leaders• 2012-13 Staff Accomplishments• Staff Training	Page 71
	Key IT Drivers and Influences for 2013-2014 <ul style="list-style-type: none">• DCRI Customers• External Drivers	Page 97

AGENDA
NIH CLINICAL CENTER
DEPARTMENT OF CLINICAL RESEARCH INFORMATICS (DCRI)
OPERATIONAL REVIEW AGENDA
MEDICAL BOARD ROOM 10/4-2551

TUESDAY, OCTOBER 1 (10/4-2551)

- | | | |
|----------------------|---|---------------|
| 8:00 – 8:30 | Background and Charge to the Review Team
<i>Review of Agenda and Introductory Comments</i> | Dr. Gallin |
| 8:30 – 10:30 | Department of Clinical Research Informatics Overview Presentation
Jon McKeeby, DSc, CIO and Chief, DCRI; Sue Houston, MBA, Chief Portfolio Officer; and David Herion, MD, Chief Medical Information Officer

<i>Presentation & discussion of mission, goals, performance measurements, and operational issues.</i> | |
| 10:30 – 10:45 | Break | |
| 10:45 – 11:00 | Overview of Survey Data from Stakeholders | Dr. Henderson |
| 11:00 – 11:30 | Tour of Facilities

<i>Dr. Henderson, CC Deputy Director for Clinical Care, will lead a tour of the Clinical Center.</i> | Dr. Henderson |
| 11:30 – 12:30 | Working Lunch with Dr. Gallin | Review Team |
| 12:30 – 3:00 | Focused Review of DCRI
<i>Dr. McKeeby will provide a tour of the department's facilities. Afterward, the team will split into 3 groups who will each conduct a more in depth review of each department/section, meeting with supervisors, and then staff. The sessions will be used to review the assigned section's operations and research support processes, staffing, skill mix, efficiency, etc.</i>

A breakout of the three-hour breakout sessions is included below:

12:30-1:00pm: Tour
1:00-2:00pm: Executive Leadership, Team Lead and Supervisor interviews
2:00-3:00pm: Staff interviews | |
| 3:00 – 4:00 | Q&A with CIO | Review Team |
| 4:10 – 5:00 | Principal Investigator/Stakeholder Interview | Review Team |
| 5:00 – 6:00 | Focused Review Debrief Session

▪ <i>Review draft report template and begin to synthesize comments.</i> | Review Team |

- *Round table debrief from each break-out group.*
- *Discuss themes and preliminary recommendations.*
- *Discuss plans for final report write-up.*
- *Review tomorrow's schedule.*

6:00 – TBD **Final Report Working Session** Review Team

Focused Review Teams will draft assigned sections of final report.

WEDNESDAY, OCTOBER 2, 2013 (10/4-2551)

8:00 – 10:00 **Finalize Recommendations** Review Team

The Review Team will finalize recommendations and preliminary report.

10:00 – 10:45 **Debrief with Chief Information Officer, DCRI** Review Team

The Review Team will summarize results of operational review.

11:00 – 11:30 **Debrief with CC Director and Chief Financial Officer** Review Team

The Review Team will summarize results of operational review.

OPERATIONAL REVIEW BACKGROUND AND PROCESS

Background

In 1998, the CC's Board of Governors, now the NIH Advisory Board for Clinical Research, was charged via their charter to review the Clinical Center's departments for operational efficiency and effectiveness. A process was developed to have both external and internal NIH experts in the particular area being reviewed dedicate a day and a half at the Clinical Center to develop recommendations on improvements in cost, productivity and effectiveness of the services under review. Experts from Academic Medical Centers and health care organizations across the country and nearly all NIH Institutes participate in these reviews.

Purpose

To review the efficiency and quality of the operations of Clinical Center Departments with the goal of containing expenditures while maximizing productivity in support of the NIH clinical research mission. A department's mission, goals, structure, service performance and budget will be assessed and evaluated in light of the Clinical Center's unique function to provide patient care in the context of clinical research and serve as a national resource for the development of innovations in the advancement of clinical research and clinical research training. Benchmarking will be a major component of these reviews, as will a critique and consultation regarding the department's internal assessment of areas of strength and opportunities for improvement. The Review Team will develop recommendations and provide observations on the department's strengths as well as opportunities for improvement in finance, clinical research, patient care and training.

Outcome

The Review Team will prepare a report identifying strengths and opportunities for improvement within DCRI which will be presented to the Chief Information Officer, Chief Financial Officer, and Director of the Clinical Center at the end of the review. The Clinical Center will prepare a point-by-point response to each recommendation and will then make a presentation to the NIH Advisory Board for Clinical Research.

CHARGE FOR THE DEPARTMENT OF CLINICAL RESEARCH INFORMATICS (DCRI) OPERATIONAL REVIEW

Leadership/Staffing

- How well do department leadership and staff support the clinical research and patient care mission of the NIH intramural clinical research programs?
- Is the department organized optimally to support the services required from CC operations, intramural clinical investigators, nursing, patients and others?
- Is the level of professional staffing appropriate for the amount of services required/delivered?
- Does the department take a strategic approach to operational management?
- Is the level of professional staffing and information technology support appropriate for the amount of care and services required/delivered?

Quality of Services

- How do NIH investigators, Clinical Center staff, and patients perceive the quality of services provided by the department?
- How are quality and performance (including timeliness) of the department's services measured? Are results optimal?

Resources/Infrastructure

- Are the right resources provided to the department to support its mission?
- Are the physical facilities of the department adequate to support its mission?
- Are there areas where the department should consider expanding/reducing/outourcing? If expansion is recommended, what resources are recommended?

Training

- What training is provided to CC and IC staff, as well as patients? What methods are utilized to provide the training—classroom, web-based, self study?
- What is the breadth and quality of the professional training opportunities provided to department staff?
- What is the breadth and quality of the educational and research training opportunities provided to students, fellows, etc?

OPERATIONAL REVIEW TEAM ROSTER

CHAIR

Rebecca D. Jackson, MD

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and Professor of Endocrinology, Diabetes and Metabolism College of Medicine,

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OPERATIONAL REVIEW TEAM BIOGRAPHICAL SKETCHES

Rebecca D. Jackson, MD
Director, Center for Clinical and Translational Science and Associate
Dean for Clinical Research and Professor of Endocrinology, Diabetes
and Metabolism College of Medicine, The Ohio State University



Rebecca D. Jackson, MD, is Director and Principal Investigator of the Ohio State University Center for Clinical and Translational Science (the academic home of the NIH-funded Clinical and Translational Science Award), Associate Dean for Clinical Research and Professor of Endocrinology, Diabetes and Metabolism in the OSU College of Medicine.

Dr. Jackson received her BS and MD degrees at The Ohio State University and completed her residency training in internal medicine at Johns Hopkins University. She returned to Ohio State for her Endocrinology fellowship and has been on the faculty since 1983. She completed formal translational research training as a junior faculty through the NIH-funded Clinical Associate Physician Award and later through a Physician Scientist Award to develop expertise in molecular biology. Dr. Jackson's research is in the area of women's health with a specific focus on elucidating genomic, proteomic and candidate biomarkers for the prediction of risk for chronic diseases associated with aging in women including hip fracture, cardiovascular disease and osteoarthritis.

She has had continuous NIH funding for more than 20 years and has been PI of two large longitudinal studies; the NHLBI-sponsored Women's Health Initiative and the NIAMS-sponsored Osteoarthritis Initiative. She has had extensive translational scientific leadership, serving as vice chair of the Women's Health Initiative since 2002, a member of the Board of Directors of the Clinical Research Forum since 2007, national secretary of the Society for Clinical and Translational Science since 2009 and co-chair of the national Clinical and Translational Science Award Consortium in 2010.

Her individual and collaborative research effects have resulted in more than 140 peer-reviewed publications. In recognition of her scientific leadership and scholarly efforts, she has been the recipient of awards including the Kellogg National Fellowship, YWCA Women of Achievement Award (1990), the Ohio Women's Hall of Fame (1991), the OSU College of Medicine Simson Research Award (1995) and the Women for Economic Leadership and Development (2009). In 2008, she was named a Fellow of the American Association for the Advancement of Science.

David Artz, MD
Medical Director, Information Systems
Memorial Sloan-Kettering Cancer Center

Dr. Artz has been CMIO at Memorial Sloan-Kettering Cancer Center in New York, NY since 2003.

In this role he has been a key member of the management team responsible for IT strategy for both clinical and research environments including vendor selection and contract negotiation, system implementation and security/privacy policy creation. He has been primary sponsor of many internally-developed applications including the Patient Portal and many electronic record enhancements. One of his major areas of focus has been the continuing development of the institution's data warehouse including a web-based self-service query tool and the incorporation of discrete data from large scale molecular testing into this warehouse. Prior to joining Sloan-Kettering David was Medical Director of Information Services at Northwestern Memorial Hospital in Chicago.



Dr. Artz has an MBA from Northwestern University's Kellogg School of Management and an MD from West Virginia University. David is a practicing internist at Sloan-Kettering with a weekly clinic.

Stephanie L. Reel, MBA
Senior Vice President for Management Systems
and Information Services
Vice Provost for Information Technologies
John Hopkins University



Stephanie Reel is the Chief Information Officer for all divisions of the Johns Hopkins University and Health System. She was appointed Vice Provost for Information Technology and CIO for the Johns Hopkins University in January 1999. She is also Vice President for Information Services for Johns Hopkins Medicine, a post she has held since 1994. As CIO Ms. Reel leads the implementation of the strategic plan for information services, networking, telecommunications, as well as clinical, research, and instructional technologies.

Ms. Reel has more than twenty-five years' experience in Information Systems, working with educators, regulators, researchers, and health care providers and payors. Under her direction, the Johns Hopkins Health System is enhancing and advancing the use of the electronic patient record and working toward a regional EPR. Johns Hopkins has been honored for innovation in information technology by the Smithsonian Institution and *Healthcare Informatics*. Also under Ms. Reel's guidance, the Johns Hopkins University has implemented self-service solutions for faculty, staff and students, leveraging the power of emerging technologies to support electronically enhanced education and research. She is a member of the Health IT Policy Committee's Information Exchange Workgroup, a federal advisory committee which serves the Office of the National Coordinator for Health Information Technology.

Ms. Reel was elected to *CIO Magazine's* 2012 Hall of Fame and named one of *InformationWeek Healthcare's* top 25 leaders driving the healthcare IT revolution. In 2009 she was appointed to President Obama's Council of Advisors on Science and Technology. *The Daily Record* recognized Ms. Reel as one of Maryland's Top 100 Women in 2008. She was named CIO of the Year 2000 by the College of Healthcare Information Management Executives (CHIME) and is a recipient of the CIO Magazine's 20/20 Vision Leader Award.

Ms. Reel is a member of HIMSS, CHIME, the Healthcare Advisory Council, the American College of Medical Informatics, and EDUCAUSE. She serves on the advisory board of *Health Care Informatics*. Ms. Reel is a member and past President of the Healthcare Information Systems Executive Association. Ms. Reel graduated from the University of Maryland with a degree in information systems management and holds an M.B.A. from Loyola College in Maryland.

Martin (Marty) Rice, RN, MS
Deputy Director
Office of Human Information Technology &
Quality, Health Resources and Services Administration
University of California San Diego

Martin (Marty) Rice, MS, RN-BC is a registered nurse and nurse informatics. He began his nursing career working in geriatric psychiatry, along with chronic and post-acute care. Since receiving his Masters in Nursing Informatics from the University of Maryland School of Nursing in 2001, he has been involved in Electronic Health Record implementation, data modeling/design, enterprise architecture, clinical quality measures, retooling clinical quality measures, and data standards.

Mr. Rice began his career in nursing informatics at North Arundel Hospital Home Health Care as their director of Information Technology where he implemented electronic charting and billing from a paper based system. In 2004, Mr. Rice transitioned to the federal government where he worked at the National Naval Medical Center (NNMC) in Bethesda, MD managing their inpatient clinical information system. In 2007, he transferred to the Centers for Medicare and Medicaid Systems in the Office of Clinical Systems and Quality, Quality Measures and Health Assessment Group. Mr. Rice transitioned from CMS to HRSA as Deputy Director of the Office of Health IT and Quality.

In May 2013, he moved to the Office of Rural Health Policy where he serves as a senior advisor. Mr. Rice is also adjunct faculty at the Johns Hopkins School of Nursing where he teaches Nursing Informatics.

Renita Anderson
Technical IT Expert (NIH OCIO)
National Institutes of Health

Ms. Anderson has served as the Director, Division of Network Systems and Telecommunications at the National Institutes of Health (NIH), Center for Information Technology in Bethesda, MD since 1997.

She manages a Division which provides voice and data services to over 30,000 customers at the NIH. Ms. Anderson is responsible for a multi-million annual budget for provisioning networking, telecommunications and cabling services. The Division of Network Systems and Telecommunications directs the engineering, design, implementation, and support of network infrastructure and services for the NIH wide area network (NIHnet) to facilitate the use of scientific, administrative, and other business applications.



The Division manages and directs NIH telecommunications systems and develops technical requirements for the NIH ICs and implements telecommunications programs to meet the needs of the NIH community. In 2012 Ms. Anderson was also appointed Senior Advisor to the Director of the Center for Information Technology. In this capacity, Ms. Anderson provides senior technical and leadership guidance to the Director across all Information Technology services overseeing operations.

Mihailo Kaplarevic, PhD
Scientific Information Officer
National Heart, Lung & Blood Institute, NIH



Dr. Kaplarevic is a well-rounded individual with broad technical knowledge in project planning and management, data management, and system performance analysis.

He has over 10 years of experience in large-scale relational, non-relational, and object-oriented databases; applied algorithms and applications; data mining and analysis; and high performance computing. Dr. Kaplarevic has published scientific articles in peer-reviewed journals in the areas of bioinformatics, cross-platform optimizations, and sequential and parallel computer architectures.

Specifically, Dr. Kaplarevic is considered a subject matter expert in large-scale data storage and mining, cloud computing, high-performance cluster computing, and cross platform porting. This expertise has been called on frequently by the National Science Foundation through participation in their biotechnology and information science panels. Dr. Kaplarevic has hands-on expert-level knowledge of a wide range of computational platforms from Windows/Linux servers to high-performance clusters to shared-memory systems.

Yang Fann, PhD
Intramural CIO
National Institute of Neurological Disorders and Stroke, NIH



Dr. Fann joined NINDS in 2002 as the Director of the Intramural IT and Bioinformatics Program overseeing the information technology support services and infrastructures as well as developing biomedical informatics research programs.

He currently leads the development of an integrated information management system, Clinical Informatics and Management System (CIMS), for clinical and bioinformatics research as well as an intramural bioinformatics facility. The system, which includes the Protocol Tracking and Management System (PTMS), has been adopted by the NIH Institutional Review Board (IRB) to electronically manage the protocol submission, review and approval process and significantly improves the efficiency of clinical research management. Currently, PTMS is used by many institutions in US other than foreign countries, such as Taiwan, South Africa, Vietnam, Phillipine, Brazil and China.

In 2010, his creation of Purchasing On-line Tracking System (POTS) to streamline and transform scientific procurement administration was quickly adopted by the NIH community, and won him the first ever HHS Innovates Award presented by the Secretary of HHS. In addition to his roles and responsibilities at NINDS, Dr. Fann serves on many NIH advisory committees including the Medical Executive Committee IT subcommittee, and the Biomedical Translational Research Information System (BTRIS) Steering Committee. He is currently a principle investigator on the Informatics Core of Center for Neuroscience and Regenerative Medicine (**CNRM**) working on building the informatics infrastructure for the National Traumatic Brian Injury (TBI) Study, a collaborative project of the DoD and NIH. In addition, his bioinformatics group has been developing several database tools, such as **Stem Cell Database** and **EvoPrinter**, to catalyze the neuroscience research.

Recently, he has co-led an international collaborative team with Dr. Matthew McAuliffe at Center for Information Technology (CIT) to build a reusable and sustainable informatics infrastructure named Integrated Biomedical Informatics System (**IBIS**) to support and catalyze biomedical research. The project was built based on existing applications and tools at NIH for scientific administration, clinical research information management and biomedical data repository (or data warehouse) with supporting tools such as common data elements, global unique identifiers, and data validations.

His current research interests are computational biology, bioinformatics, clinical research informatics and applying information technology for advancing translational biomedical research.

SECTION 2

DCRI OVERVIEW

The Department of Clinical Research Informatics is responsible for:

- Translating business requirements into working components of our clinical information systems.
- Implementing systems and enhancements that focus on the facilitation of clinical research workflow and seeking opportunities to improve clinical processes while enhancing system functionality.
- Incorporating NIH, HHS, national data, decision support, and communication standards into system development to facilitate clinical care, system interoperability, and research.
- Developing data interfaces between systems to promote data integrity and highly available and consistent data between systems.
- Managing system implementation risk through a robust testing process, which includes the translation of functional requirements into functional test cases, and the development of test scenarios from “day in the life” business processes.
- Developing custom functionality within the Hospital Information System to support clinician workflows, enhance clinical decision support, and integrate data from other systems.

ADMINISTRATIVE SYSTEM DEVELOPMENT AND SUPPORT

Administrative System Development and Support focuses on providing administrative systems that streamline and enhance workflow processes and allow user-friendly access to reliable data that assists in the transformation of data into information and knowledge that facilitate sound decision making. Examples of administrative systems include Admissions-Travel-Voucher (ATV), the Occurrence Reporting System, applications for Patient Recruitment to manage the recruitment process (from potential patient contact to payment of healthy volunteers), and the Data Transformation Initiative. A complete list is reviewed under the Technologies Section. This area also focuses on:

- Translating business requirements into working components of our administrative information systems.
- Designing systems that focus on the facilitation of workflow and seeking opportunities to improve processes while enhancing system functionality.
- Supporting NIH clinical researchers and Clinical Center (CC) departments in achieving their goals by assisting them in all areas of software systems development, management and procurement.
- Supporting development and implementation of CRIS Administrative applications through integrated testing, delivery of instruction and facilitation of customer utilization of applications to support the workflow of administrative processes.

TECHNICAL INFRASTRUCTURE/DATA CENTER MANAGEMENT

Technical Infrastructure/Data Center Management focuses on providing a secure, dependable technical environment that supports the increasing requirements that evolve with improving clinical and administrative systems. This area also focuses on:

- Maintaining a high availability of critical computer and networking systems and providing prompt, courteous technical support in a cost effective and timely manner.

- Providing comprehensive networking support that anticipates, meets, and exceeds our customer's service level agreements in a dynamic operational environment.
- Ensuring computers, printers, and communication devices are available and managed effectively to support CC departments and NIH research.
- Supporting and promoting the goals of DCRI by seeking and engaging in active research and collaborative work within the NIH community as well as with academia and industry - work in which knowledge in the biomedical and computing sciences is advanced, and from which practical results that directly lead to better health care for everyone are realized.

CUSTOMER SUPPORT

Customer Support focuses on enhancing customer satisfaction in the areas of clinical and technical support, including:

- Providing customer-focused and staff-focused, quality IT services and technical support which assists our customers in making the best use of the newest biomedical technologies and existing information technologies in support of their business function.
- Supporting development and implementation of CRIS applications through delivery of instruction and facilitation of customer utilization of applications to support the workflow of clinical research studies and care.

SECURITY & PRIVACY

Security and Privacy focuses on the security of all clinical, research and administrative systems and maintains the privacy of sensitive confidential information related to patients, employees and contractors contained therein according to the requirements established by the Privacy Act of 1974. While most systems are under the control of DCRI Technical staff, the team is also responsible for ensuring the security and privacy of systems under the control of CC departments and third party applications hosted off-site. This area also focuses on:

- Providing protection of sensitive information by ensuring the "Confidentiality, Integrity and Availability" for all clinical and administrative systems.
- Conducting Security assessment & Authorizations (SA&A) on CC IT systems to include: security control testing, risk assessments, system security plans, Plan of Action & Milestones (POA&M) documentation, contingency plans, and configuration management plans. All CC IT Systems, Data Centers and Networks in the CC's system inventory undergo the SA&A process and achieve an Authority to Operate (ATO).
- Continuously monitoring the security and privacy of IT systems for effectiveness and consistency with pre-established requirements as related to established NIST, OPM, and NIH standards.
- Ensuring CC staff complete Annual Security Awareness and Privacy Awareness training.
- Ensuring CC staff with significant responsibility complete HHS Role-based Information Security courses.
- Completing Privacy Impact Assessments (PIA) for all CC IT systems using HHS tools, to ensure the protection of personally identifiable information (PII). Reporting on PIA completion and other related information to HHS and the Office of Management and Budget (OMB) in par with the Federal Information Security Management Act (FISMA) is also accomplished.
- Providing consultation on security and privacy throughout the lifecycle of new and existing CC IT systems; i.e., procurement, design, development, implementation, operations & maintenance and disposition.
- Investigating, reviewing and reporting on all potential privacy act violations involving CC Systems and CC staff.

- Investigating, analyzing, remediating, and reporting on all security vulnerabilities identified by the CC and NIH.
- Investigating and responding to all security and privacy incidents in the NIH Incident Response Team (IRT) Portal within established timeframes.
- Providing expert consultation of matters related to privacy, security and confidentiality, including legislation, regularity requirements and organizational standards.

TRAINING & OUTREACH

Training and Outreach focuses on:

- Providing training and communication outreach to CRIS users, stakeholders and internal department members.
- Providing training and clinical support to system users, evaluating performance and effectiveness of system use, developing clinical research informatics training programs and fostering collaboration to advance knowledge.
- Developing and facilitating curriculum for internal and external training programs/fellowships, planning improvement strategies for support of clinical operations, and directing system evaluation initiatives including prototype testing, performance measurements, and satisfaction surveys.

SECURE COMMUNICATION WITH PATIENTS, NIH CARE PROVIDERS, AND OUTSIDE/REFERRING PHYSICIANS.

This business area was initiated in 2009 to focus on the secure communication of Clinical Information to patients, NIH care providers and outside/referring physicians. FY2013 priorities include secure communication between patients and the NIH Care Team within the CC Patient Portal. In FY2014 secure messaging with Referring Physicians and a Referring Physician Portal will be pursued.

ORGANIZATIONAL STRUCTURE

The staff of the Department of Clinical Research Informatics (DCRI) is dedicated to the mission of the NIH Clinical Center. The DCRI staff is divided into multiple teams, which provide an array of services to support the technical architecture of the Clinical Research Information System (CRIS) and its many clinical applications. In addition, DCRI staff support users from across the NIH who depend on CRIS to conduct research and to manage patient care.

Organizational Charts

Figure 2-1. Top Level Organization Chart

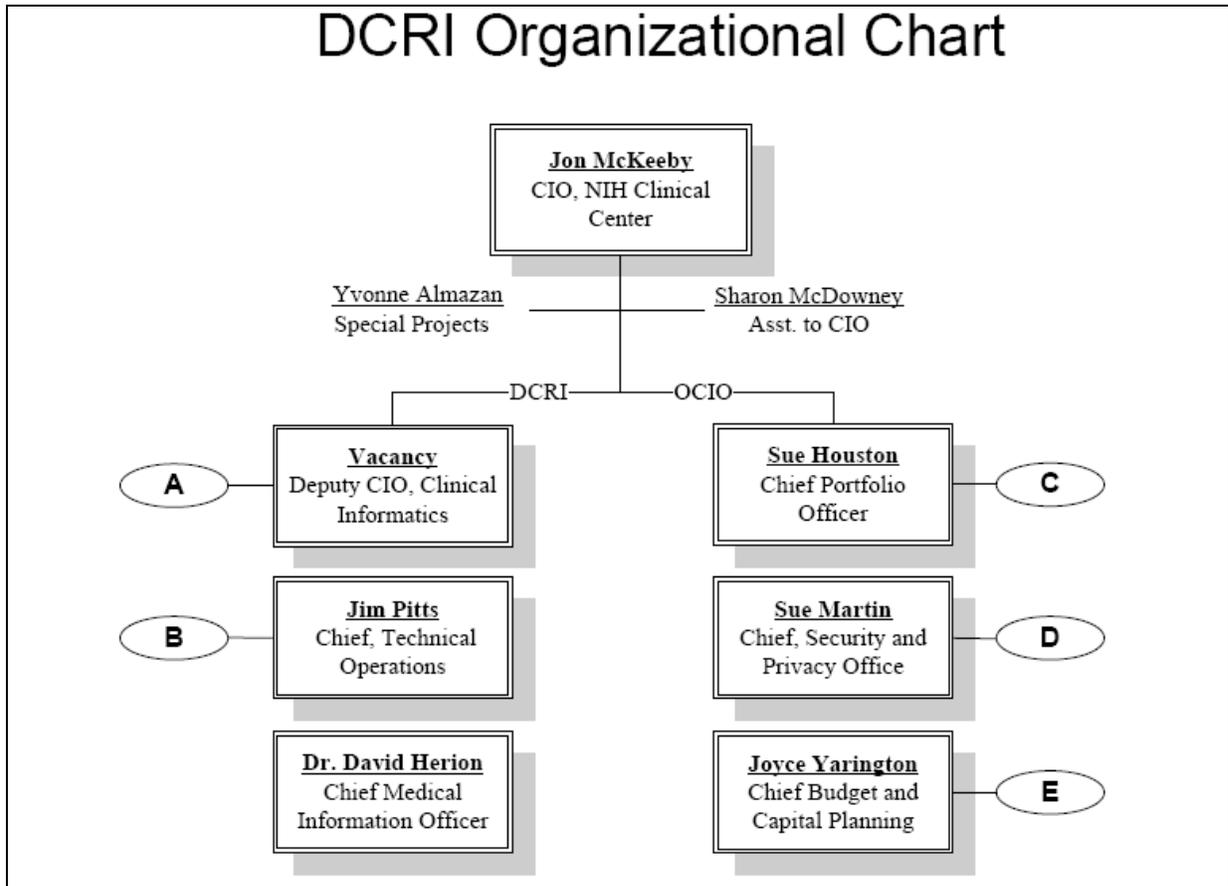
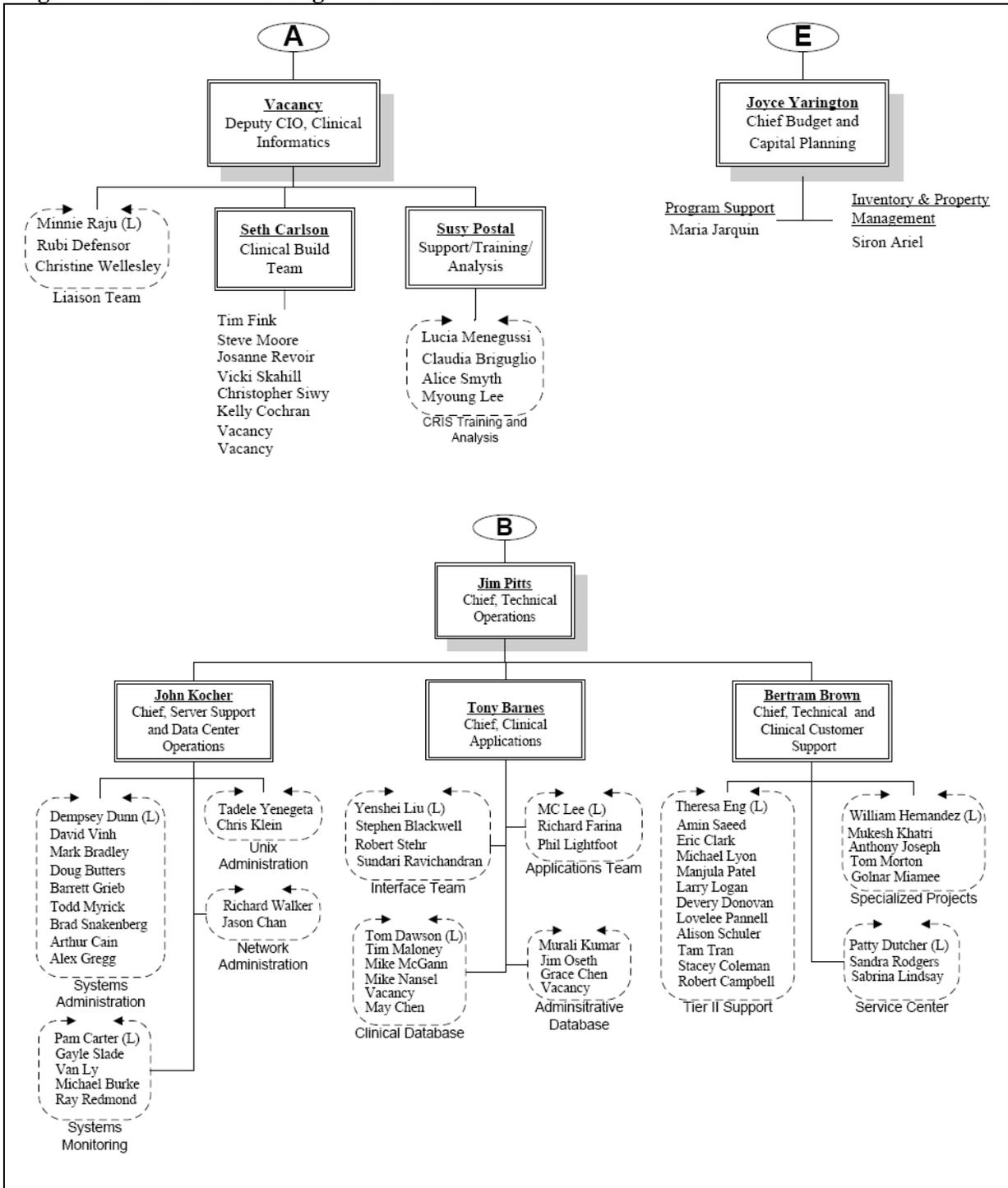
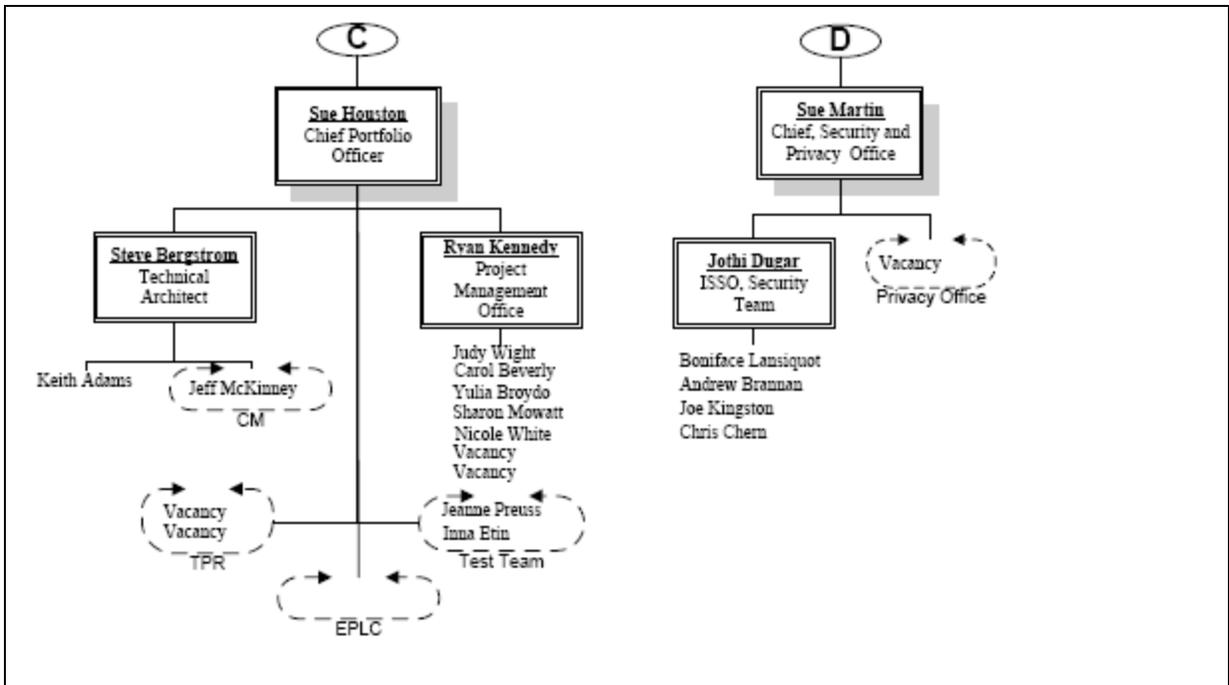


Figure 2-2. Section Level Organization Chart





Section Descriptions

CIO Office

- **Chief Medical Information Officer (CMIO)**

The CMIO is the CRIS User and Clinical IT Systems advocate at the CC. The CMIO is the DCRI executive responsible for the CRIS Prescriber Group, as well as the DCRI representative for the Clinical Fellows Committee and Medical Executive Committee (MEC) IT subcommittees. The CMIO also participates in a variety of regular meetings where prescribers and IC clinical research staff meet, such as monthly QA meetings, business, as well as clinical rounds, and other standing CC Committees such as the Surgical Administrative, Pharmacy and Therapeutics and Pediatric Care Committees. Other *ad hoc* meetings with physician and mid-level practitioner colleagues are routine and important events for discovery of CRIS and other IT issues. In aggregate, these activities typically involve clinicians and clinical research teams (clinical research nurses, protocol coordinators, data managers, etc.) from IC's and provide a forum for two-way discussion of clinical IT issues, especially those potentially involving business process or important IT changes.
- **Clinical Informatics (A under organizational chart)**

The Clinical Informatics team provides support to CRIS users throughout all phases of the system development lifecycle: Planning, Design, Build, Training, Testing, Implementation, Maintaining, Support and Evaluation. Members of this team possess clinical and process knowledge, enabling them to provide valuable data, information and insight to the Clinical Center's care providers who use the CRIS System. The CRIS Support team is responsible for addressing CRIS user issues both proactively and reactively to ensure "at the elbow" help is available when necessary. This same group provides and manages all CRIS training, both in the classroom and online. Another section of this team configures the CRIS system to enhance and customize its ordering and documentation screens, and to improve its functioning. As new protocols are developed, this team addresses changing research and departmental needs through newly configured items. Our custom developers create technical solutions to complex processes that often require the identification of a new process and the implementation of a technical process to import and organize disparate data elements that need to be displayed in a way that provides the right information, at the right time, to the right care provider. They help to provide access to evidence based information from within CRIS.
- **Portfolio Office (C under organizational chart)**

The Portfolio Office provides the processes around managing CC applications and projects from inception to disposition following the OMB Enterprise Performance Life Cycle framework. The Portfolio Office works in partnership with the IT Advisory Group (ITAG) to evaluate, prioritize and schedule new projects and initiatives.
- **Security and Privacy Office (D under organizational chart)**

The Security and Privacy Office assures all administrative and clinical systems within the NIH Clinical Center comply with the NIH Enterprise Information Security Plan and respective government regulations in order to protect the organization's sensitive data. The operations staff investigate security vulnerabilities, working with users and technical staff to mitigate the risk to the organization. The Clinical Center Privacy Officer ensures CC systems protect individually identifiable information in accordance with The Privacy Act. The Clinical Center Information Systems Security Officer is responsible for ensuring the security of the Clinical Center's IT systems.

- **IT Budget & IT Capital Planning Office (E under organizational chart)**
The IT Budget and Capital planning office is responsible for the purchase of the Clinical Center IT equipment and IT-based maintenance contracts as well as the planning, purchasing, and deployment of CERC-IT. The office also manages the distribution of wireless devices and its vendor contracts. The office maintains a stock of standardized IT equipment that departments can purchase throughout the year.

Clinical Informatics (A under organizational chart)

- **CRIS System Configuration**
These team members configure a wide range of components in the clinical system including orders, order sets, clinical documentation, results, ADT/registration functions, application security and environmental profile settings. This team also incorporates NIH, HHS, other regulatory agencies, decision support, and communication standards into system development to facilitate clinical care, system interoperability, and research.
- **CRIS Custom Programming**
These team members design, build and implement custom solutions to address requirements necessary to support the clinical care and patient research activities in the CRIS system. Some of the work includes: Medical Logic Modules (MLMs), Custom tabs (Protocol Info, ICD9, Appointments, Meds View) using Objects Plus programming.
- **Implementation Support**
Several members of this team provide support before, during and after system implementations. This includes implementations of new systems, large system upgrades and smaller system enhancements. It includes activation planning and communication surrounding the implementation as well as being on-site during implementations to support end users through downtime and recovery.
- **CRIS Education and Training**
DCRI's CRIS training team provides education to all system users prior to giving them access to the system. This includes in-classroom training for all CRIS users that covers key concepts of system use: Introduction to CRIS (general navigation, result and clinical documentation retrieval), Order Entry, Clinical Documentation, Electronic Medication Administration Record and Printing. These same concepts are also supported by this team via an online system for our prescriber community. They keep all educational materials up to date, provide just in time training to end users and conduct advanced system training for our more savvy users.
- **Business Process Analysis**
Several members of the informatics team spend time with customers, assessing their needs and observing their processes as they interact with clinical systems in order to gather and define clear requirements that can be implemented as a new technical solution or as an enhancement. The team also facilitates workflow analysis and process redesign for new projects and clinical needs involving CRIS.
- **CRIS Reports and Analytics**
This team develops and disseminates a variety of reports and data queries. They work with end

users to develop reports available via CRIS to support clinical and research care of the patient. They also work with researchers and administrators to pull data from our various systems to provide information that is used to assess current status, look for trends and improvements and provide research data.

- **Customer Support**

Members of this team provide both proactive and reactive support to our end user community. They respond to calls for assistance that are clinical in nature and strive to provide exceptional customer service. They have also developed methods to reach out to users routinely by conducting unit CRIS rounds, manning a CRIS Booth and facilitating User Group meetings. They communicate and educate system changes on an ongoing basis both internally and to our end users.

- **Outcomes and Evaluation**

This team's focus is to assess the effectiveness of system implementations and enhancements. They work to identify priority areas to evaluate, collect data and report findings in order to recommend and implement system improvements. They include members from other sections within the department as well as key external stakeholders.

- **Clinical Documentation/Liaison**

This team supports electronic clinical documentation to multi-disciplinary clinicians (from nursing to ancillary to physicians) and researchers throughout the Clinical Center and NIH Institutes. They configure and create clinical documentation allowing clinicians to electronically document on patients at the point of care, providing valuable data required to make educated clinical decisions in the delivery of safe and efficient patient care. They ensure governance and healthcare mandates are successfully incorporated into clinical documents while implementing standardization. The team accomplishes their mission through collaboration, effective bi-directional communication, education and training, facilitating system enhancements, establishing process improvements, quality controls, while maintaining industry best practices of clinical standards of care.

Technical Operations (B under organizational chart)

- **Applications Team**

The Custom Applications Team develops custom applications for users. This team supports the software development life cycle from idea conception, procurement, planning, design, development, testing, activation, operations and maintenance and retirement. Applications designed, developed and maintained include the Department of Lab Medicine (DLM)/Department of Transfusion Medicine (DTM) Test Guide, Occurrence Reporting System, Hospital Services, Recruitment Volunteer System, multiple course registration systems, Credentialing System, Protocol Tracking and many others.

- **Databases**

The Databases Team supports the database servers used to provide the Clinical and Administrative systems supported by DCRI. This includes multiple Oracle, MS SQL Server and Sybase database servers. Examples of clinical systems supported include CRIS Sunrise, the Surgical Information System, Pharmacy systems (ScriptPro, Omnicell), the Nutrition System CBORD and many others.

- **Interface**

When an item is ordered or a patient is registered, the data is sent to multiple Ancillary Systems. When the item is resulted, the data is then sent back to CRIS Sunrise. This data interoperability is provided through HL7, File and XML interfaces. The Interface team is comprised of staff that plan, document, design, implement, test and activate these interfaces. Systems that are interfaced with CRIS Sunrise include the Laboratory Information System (LIS), Radiology Information System (RIS), the EKG system, the NEI clinical system, the NIAID CRIMSON system, and many others.
- **Network Administration**

The Network Administration team operates in a very dynamic environment and provides comprehensive support to anticipate, meet, and exceed customer's requirements. The Networking team is responsible for all data communication entering/leaving/resident in the Clinical Center Data Center which includes administration of firewalls, DMZ, routers, switches, VLANS and VPNs. The Networking team is also responsible for DCRI network connectivity from the Clinical Center edge router interface right to the wall plate of each user within the Clinical Center.
- **Systems Administration and Data Center Management**

The System Administration and Data Center Management teams enhance productivity at the Clinical Center by providing reliable access and prompt support of computer systems and their associated applications. The teams maintain over 600 hundred servers and other pieces of computer related equipment in the Clinical Center Datacenter. Services and systems supported include basic network services (such as email and file sharing), remote access, CITRIX, Nutrition, Pharmacy, CRIS, and related ancillary systems.
- **Systems Monitoring**

The Systems Monitoring team ensures the consistent, reliable availability of critical computer and networking systems by monitoring all operational clinical systems. Team members provide 24/7 technical user support and communicate with users regarding any CRIS system interruptions.
- **Technical Customer Support**

The Technical Customer Support team provides customer-focused IT services and technical support to users. The team includes a Service Center, Tier II Support and a Special Projects section. The team supports over 5,000 devices within Clinical and Administrative areas. This includes the support of desktop computers, laptops, the standard clinical desktops, workstation on wheels (WOWs), barcode devices, and mobile devices.
- **Unix Administration**

The Unix Administration team provides support to multiple IBM, SUN and LINUX Unix Based Systems in operation within the CC. The team maintains over 60 servers and other pieces of computer related equipment in the Clinical Center Datacenter. Services and systems supported include basic database support, SunRay access, custom application support and website management.

Portfolio Office (C under organizational chart)

- **Enterprise Architecture**

The Enterprise Architecture (EA) Office integrates business processes, information technology and application architecture to ensure each are aligned to CC and DCRI organizational strategies

and operational activities. Major duties include evaluating new projects and application requests, verifying technical system compliance to NIH guidelines, developing technical options for IT solutions, identifying the technology road map, and developing an IT strategy for progress on CC and DCRI goals and objectives.

- **Configuration Management**

The Configuration Management (CM) team provides a standard methodology for change management of all configurable items in CC applications. These system changes are limited in scope and work effort, but still require a formal process from request through approval, development, testing and migration between environments. The CM team works closely with the PMO for tracking changes that are included in projects.

- **Project Management Office**

The Project Management Office (PMO) is responsible for defining and maintaining a standard methodology, based on industry best practices, for the planning and execution of all Clinical Center IT projects. The PMO is comprised of a tightly integrated team of project managers and system analysts who lead the coordination, documentation, and implementation of projects undertaken by DCRI. With a focus on skillful communication and customer outreach, the PMO provides education, guidance, and tools to leads of initiatives and projects throughout the CC.

- **Test Team**

The Test Team provides testing support for CC projects and configuration management activities. Major duties include consulting with customers to define testing scope and objectives, developing a test plan, testing scripts and scenarios based on system and process requirements, and ensuring the proper testing of all systems components.

Budget & Capital Planning (E under organizational chart)

- **Budget & Capital Planning**

The mission of Budget and Capital planning is to manage the DCRI, Telecom, and CERC-IT budgets, facilitate and manage all the CC IT purchases and deployments for devices, services, and maintenance contracts. Prepare all the statements of work and other supporting documentation in support of the IT purchases and contracts. Ensure and the vendor maintenance contracts are funded and in place to support the mission critical IT systems at the CC

- **Program Support**

The mission of the Program Support team is to enhance productivity within the department by providing effective and timely administrative support to DCRI staff, leadership, and project teams.

- **Inventory & Property Management**

The mission of the Asset Management team is to assure that computers, printers and communication devices are available and managed effectively to support DCRI and other Clinical Center departments, as well as research initiatives conducted at the Clinical Center.

- **Security Team**

The Security team is made up of an Information Security Officer (ISSO) and alternate ISSOs that

assure all administrative and clinical systems within the NIH Clinical Center comply with the NIH Enterprise Information Security Plan and respective government regulations in order to protect the organization's sensitive data. The operations staff investigates security vulnerabilities, working with users and technical staff to mitigate the risk to the organization to include the system/application, server, networks, and workstation levels.

- **Privacy Team**

The Clinical Center Privacy Officer ensures CC systems protect individually identifiable information in accordance with The Privacy Act. The Privacy Officer collaborates with the NIH Office of the Senior Official for Privacy to develop/maintain System of Record Notices and Privacy Impact Assessments for CC IT systems and Third Party Web Applications that collect personally identifiable information and responds to quarterly and annual FISMA data calls. The Privacy Officer advises CC staff on privacy issues, ensures completion of privacy awareness training and fosters the adoption of privacy policy and procedures within the CC. In collaboration with the IT system owner, the Privacy Officer responds to request for records and investigates complaints from individuals who believe their PII has been inappropriately obtained, used, disclosed, or may be inaccurate. In collaboration with NIH Incident Response Team, the Privacy Officer is responsible for the documentation to NIH and HHS related to security incidents involving loss of PII and suspected breaches of PII.

Special Services

- **DCRI Store**

The DCRI Store is a service where departments can order both stock items such as the CC standard configuration desktop, laptops, and special order items like software applications, special computer and laptop configurations as well as other IT specific items

- **ITC**

The Clinical Center Information Technology Center (ITC) provides NIH Clinical Center employees with the latest technologies supporting clinical research and patient care. The center was developed to provide Clinical Center employees with sophisticated computing resources. Many departments within the Clinical Center cannot justify the purchase of high-end equipment and have been forced to complete projects through less efficient means. The Clinical Center recognized this need and has responded with a resource center in Building 10. The ITC, located on the basement level of the Clinical Center (B1S235), is equipped with computers, color printers, poster printers, scanning devices, slide makers, and other equipment. An ITC staff member is available to answer questions and assist with projects. Any user entering the ITC will have access to any available computer equipment and a knowledgeable staff person. You will get assistance with special projects, computer-based training, and file and image conversions. NIH Clinical Center employees can expect to have access to a full array of specialized computing resources and to receive high quality support from the ITC.

SECTION 3

CLINICAL RESEARCH INFORMATION SYSTEM (CRIS)

CRIS

The Department of Clinical Research Informatics (DCRI) is responsible for management of applications and information technology for clinical research. DCRI collaborates with departments across the NIH Clinical Center (e.g., Nursing, Pharmacy, Radiology, Laboratory Medicine, and Transfusion Medicine) as well as multiple institutes that bring their patients to the NIH CC with the shared focus on the Clinical Research Information System (CRIS).

CRIS is the primary computer information system used to support patient care, research, and administrative activities in the Clinical Center. CRIS is based on the Allscripts Sunrise Acute Care Manager 5.5 SP1. CRIS is used directly by physicians, nurses, and ancillary and administrative staff in performing a variety of information tasks related to patient care. Tasks include:

- Managing admissions, transfers and discharges
- Managing patient registration
- Maintaining patient demographic data
- Maintaining patient protocol information
- Providing bed management
- Writing all medical orders
- Attributing of medical activities (orders, appointments and documents) to a specific research protocol
- Retrieving laboratory results
- Retrieving radiology results
- Documenting of patient care plans
- Documenting of vital signs
- Documenting of medication administration
- Documenting of intake and output
- Documenting of progress notes
- Reviewing of outside documentation

Approximately 90% of the Clinical Center's medical record content is generated from CRIS. The 10% not in CRIS are contained in Institute and Center (IC) systems that currently do not interface to CRIS and handwritten progress notes from the outpatient clinic areas.

The original architecture of CRIS was based on Dr. Rosenfeld's (NIH CC's CIO when CRIS was implemented) CRIS Flower Diagram (Figure 3-1.) which shows that all systems connect together representing the various business requirements of the Departments and Institutes/Centers.

Over 2,750 users access CRIS daily using over 600 Standard Clinical Desktops (280 Desktops, Workstations on Wheels (WOWs)), 300 Sunray Workstations and hundreds of remote computers that utilize CITRIX. Over 400 printers produce output ranging from work lists, medical care plans, lab specimen and pharmacy labels and permanent medical record documents.

Departmental Ancillary Systems

The NIH Clinical Center hosts numerous information systems that support individual hospital departments and functions. Uni-directional and bi-directional interfaces are used to support the flow of data between CRIS and the Ancillary Systems. For example, the Radiology Information System (RIS)

receives orders from CRIS with status message results being reported back to CRIS. The overall goal is to configure CRIS so that all clinical information needed to support patient care is available via one system – CRIS.

Figure 3-2 depicts the major current state of Ancillary Systems which interact with CRIS within the NIH Clinical Center, with their major functions and data flows. Each department is responsible for the administration of system content, while DCRI is responsible for maintaining the system hardware and interfaces with CRIS.

Electronic Health Record (EHR) Background

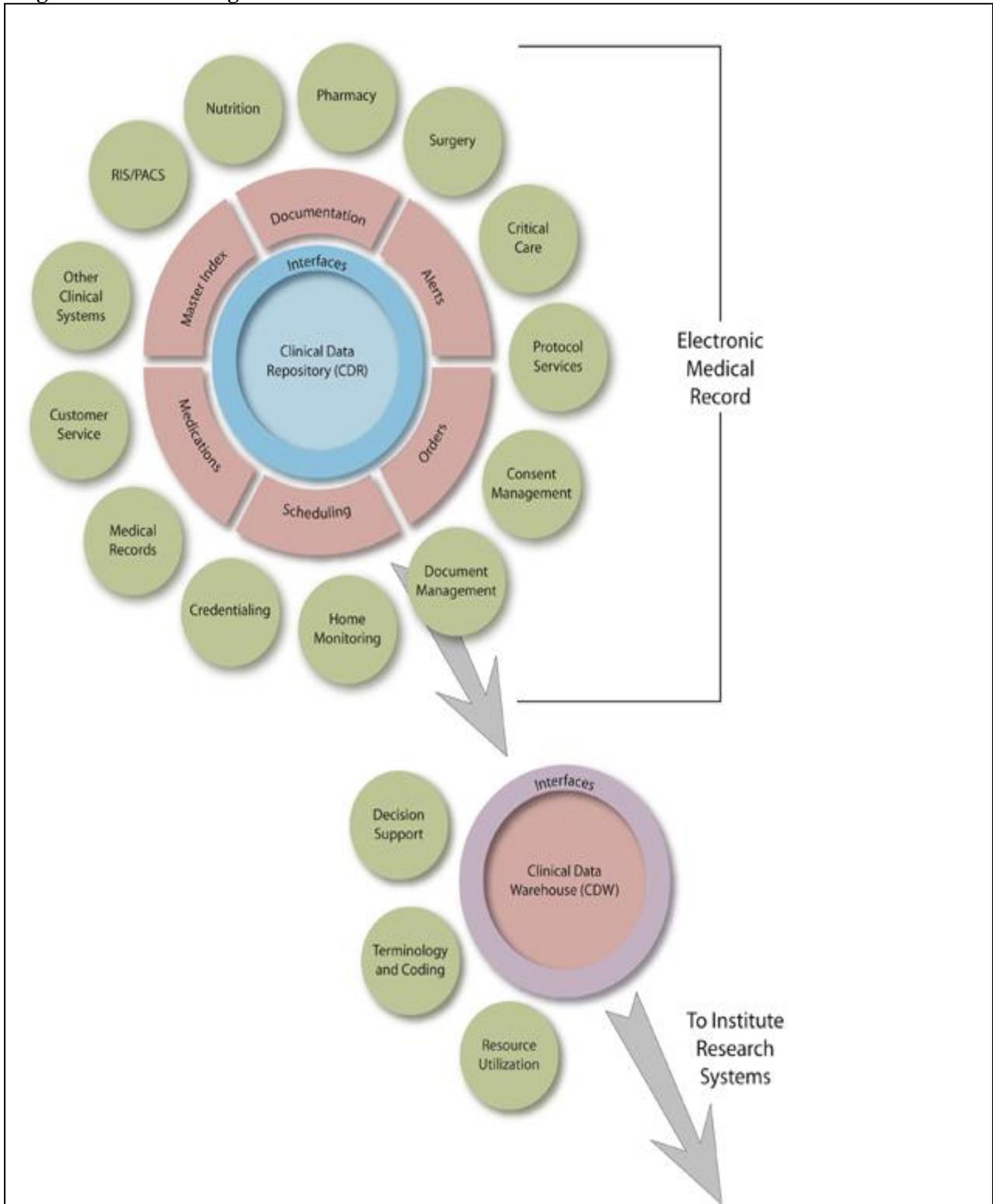
The EHR journey for the NIH Clinical Center (NIH CC) began back in 1975 with the implementation of Technicon's system that we called the "Medical Information System" (MIS). It was a mainframe hospital information system whose servers took up the majority of the basement level of the Clinical Center. Clinicians accessed MIS originally through dummy terminals with light pens. All text on the monochromatic screen was in block capital letters and when one item was selected, the screen would move along a linear path to the next appropriate screen. Order entry and clinical documentation were entered via MIS. You could say we were early adopters of Computerized Physician Order Entry (CPOE) before it was even called CPOE. MIS interfaced with the lab system and was integrated into the workflows of the radiology and pharmacy departments. Since all patients at the CC are on research protocols, the system had to be customized to support both clinical care and complex scenarios with investigational treatments and medications.

As EHR technology advanced, it was clear that we would need to make a change in order to take advantage of available IT capabilities that MIS could not provide. We needed a relational database that offered enough flexibility to support research and clinical care as well as to provide improved methods of storage, querying, and bringing together and sharing the clinical and research data contained within.

In 2001, we began planning for the replacement of MIS, now known as the Clinical Research Information System (CRIS). CRIS, at its core, is a vendor based system provided by Allscripts. It was selected for its flexibility and scalability, which was needed to support a combined clinical and research environment. In addition, it was selected for its ability to electronically interface with other clinical systems. We went live with a "Big Bang" implementation in August, 2004.

We then "officially" had CPOE with an emphasis on order entry by our physicians, and are now consistently at the 90% mark for medications ordered. We started with approximately 800 protocol order sets built in CRIS and now support over 1,500 active research protocols, many with investigational medications that require more sophisticated security settings. Clinical documentation has been in our EHR for our nurses and ancillary departments since the 1970s, but has flourished in the last 6 years with improved support of workflows and clinical decision support elements. Our physicians began their on-line documentation journey in 2009 with a small pilot that has now become the norm. The ability to efficiently pull data from other locations in the chart into progress notes has been key to adoption. Barcoding for specimen collection and blood transfusion verification have not only increased our ability to provide accurate research data, but have improved patient safety as well. We now have over 100 interfaces developed to exchange data so that is available in the right place, at the right time, to the right care provider, for the right patient.

Figure 3-1. CRIS Diagram



CRIS Usage

Table 3-1 reviews the usage of CRIS based on orders placed, results place medication administrations, documents authored, etc. The increase in Radiology Results posted for 2013/2013 was based on resending results to allow the link to PACs for images. Table 3-2 reviews the CPOE usage for 2011-2013. Table 3-2 reviews the CPOE usage for 2011-2013.

Table 3-1. CRIS Usage Activity (note: “Major Item” refers to “Major Activity”)

CRIS Major Item Statistics Yearly Summary Report

Yearly Summary: 1/1/2004 to 8/31/2013

Major Item (Total #)	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013#
Orders Placed	2,402,746	1,748,207	1,685,896	1,740,777	1,737,044	1,924,618	1,891,879	2,159,818	2,380,889	1,665,125
Lab Orders Placed	1,802,392	924,783	869,655	876,822	864,370	956,767	940,378	1,114,569	1,365,126	923,439
Active Lab Orders w/Results	1,699,713	637,473	621,262	628,055	621,416	685,846	677,770	816,466	1,022,645	670,863
Lab Test Results Posted	11,482,900	4,265,639	4,129,617	4,298,079	4,453,778	5,566,842	5,739,589	6,067,205	6,291,259	3,630,190
Radiology Orders Placed	152,288	86,494	88,468	88,367	84,621	91,837	91,407	95,561	90,904	138,252
Active Radiology Orders w/Results	142,314	58,348	60,338	59,447	56,887	61,428	59,918	63,304	59,764	115,863
Radiology Test Results Posted	141,555	59,305	61,651	64,897	64,176	68,689	78,063	80,615	320,050	208,401
Pharmacy Orders Placed	156,509	398,279	387,395	388,669	388,831	424,577	419,434	465,302	423,781	269,722
Medication Administrations	169,735	492,969	542,682	567,279	554,029	667,809	671,725	703,811	659,381	395,201
All Other Orders Placed	291,557	338,651	340,378	386,919	399,222	449,417	440,660	484,366	501,078	333,712
All Other Active Orders w/Results	199,100	84,118	79,901	84,523	87,825	101,589	94,570	101,128	108,020	64,119
All Other Test Results Posted	660,780	272,160	280,069	330,969	381,981	393,866	388,494	419,304	442,662	296,823
Physician Progress Notes Authored	4	79	152	4,244	34,134	74,394	84,552	99,853	107,394	73,353
All Progress Notes Authored	4	79	153	5,873	45,472	106,342	128,413	154,440	162,823	113,946
Interdisciplinary Notes Authored	668,588	1,739,235	1,906,533	2,098,256	2,146,430	2,441,107	2,298,977	2,051,473	1,949,473	1,292,097
Inpatient Admissions	2,569	6,403	6,047	5,694	6,058	6,452	5,960	6,089	5,690	4,022
New Outpatients	10,106	7,620	7,562	7,555	8,077	9,244	9,226	10,231	10,102	6,648
Inpatient Transfers	1,584	3,783	3,205	3,275	3,630	4,097	3,637	3,843	3,384	2,427
Outpatient Census	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Inpatient Census	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Physician Placed Orders	2,205,694	782,135	708,912	724,887	723,944	794,331	761,472	836,322	887,500	639,929
Agent for Placed Orders	2,136,816	686,517	617,020	632,626	625,417	700,779	707,314	804,598	931,137	710,544
Order Requisitions Generated*	0	0	0	0	0	0	0	0	0	90,999
Labels Generated*	0	0	0	0	0	0	0	0	0	51,438
Reports Generated*	0	0	0	0	0	0	0	0	0	189,445
Yearly Distinct User Logins	2,803	3,402	3,477	3,562	3,623	3,855	4,057	4,269	4,375	4,106

- YTD as of 8/31/2013

* - 8/3/2013- 8/31/2013

Table 3-2. CRIS CPOE* Statistics

Year	Number of Medication Orders	CPOE Medication Orders	Total Number All CRIS Orders	CPOE All Orders
2011	37,090	87.9%	154,545	65.7%
2012	34,710	90.9%	174,870	62.3%
2013	32,976	90.4%	178,692	61.2%

*Computerized Practitioner/Physician Order Entry

Healthcare Information and Management Systems Society (HIMSS Analytics) EMR Adoption Model
 Healthcare Information and Management Systems Society Analytics (HIMSS) has devised an EMR Adoption Model. This is an 8-step process that allows tracking of EMR adoption progress against healthcare organizations across the country. All scores are stored in the HIMSS Analytics® Database. Each stage shown in Figure 3-2 represents the amount and complexity of the IT systems that are in place (i.e., CPOE, electronic clinical documentation, integration with lab, pharmacy, radiology, etc.) at that level. The higher the level, the more sophisticated and integrated the IT systems.

27% of U.S. Hospitals are at level 5, ~14% are at a level 4, and the remaining 59% are at a level 3 or lower. The NIH CC is currently at level 4; that being said, we have accomplished components of Level 5, 6 and 7. The Clinical Center will reach level 5 after we implement medication barcoding, which is scheduled for mid-2014 (as the first phase, medication barcoding will be implemented in two clinical units in November 2013). The Clinical Center will reach levels 6 and 7 by making all progress notes electronic; we are currently working on the development of progress notes for outpatient clinic areas and will then request a mandate from the Medical Executive Committee that all progress notes are electronic in 2014. **Table 3-3 provides detailed information on the process.**

Table 3-3. HIMSS* Analytics Stages Annotated with NIH CC Systems

Stage	Description	NIH CC/CRIS	Done
7	The hospital has a paperless EMR environment. Clinical information can be readily shared via Continuity of Care (CCD) electronic transactions with all entities within health information exchange networks (i.e., other hospitals, ambulatory clinics, sub-acute environments, employers, payers, and patients). This stage allows the health care organization to support the true sharing and use of health and wellness information by consumers and providers alike. Also at the stage, HCO's use data warehousing and mining technologies to capture and analyze care data, and improve care protocols via decision support.	NIH CC does not currently bill thus those items currently do not apply. A Data Repository which is known as NIH Biomedical Translational Research Information System (BTRIS) with data from the CRIS its predecessor MIS, and multiple institute systems data has been created and is available for data mining and research.	
6	Full physician documentation/charting (structured templates) are implemented for at least one patient care service area. A full complement of radiology PACS systems is implemented (i.e., all images, both digital and film-based, are available to physicians via an intranet or other secure network.)	Progress notes are now all entered via CRIS for inpatients. Outpatient charting is 50% on-line with a goal to reach 100% by the end of the year. Transcribed reports such as history and physical, discharge summary, operation notes, consult reports and first-time outpatient reports are transcribed in a transcription system and interfaced to CRIS. PACS is currently a separate system with no link to CRIS. However, images are now available via what we call "RADLite" from the Results tab in CRIS	
5	The closed loop medication administration environment is fully implemented in at least one patient care service area. The eMAR and a barcoding or other auto-identification technology, such as radio frequency identification (RFID), are implemented and integrated with CPOE and pharmacy to maximize point of care patient safety processes for medication administration.	A barcoding project which has been completed for patient identification, specimen collection, and blood product infusions. The Outpatient medication prescription process is a closed loop with all orders in CRIS interfaced to the Outpatient Pharmacy system (ScriptPro) and processed by Pharmacy. The Inpatient and in-house outpatient clinic and day hospital Medication administrations barcode will be completed calendar year 2014 with a pilot scheduled for November 2013 for two Inpatient units.	
4	Computerized practitioner/physician order entry (CPOE) for use by any clinician added to nursing and CDR environment. Second-level of clinical decision support related to evidence-based medicine protocols implemented. If one patient service area has been implemented CPOE and completed previous stages, this stage has been achieved.	For 2011, 87.9% of medication orders (N= 37,090) and 65.7% (N= 154,545) for all orders. 2012 there was 90.9% medication orders (N= 34,710) and 62.3% (N= 174,870) for all orders. Then 2013 to date totals are 90.4% of medication orders (N= 32,976 and 61.2% (N=178,692) for all orders. The total number of orders has increased with the number of medication orders decreasing. The total percent for medication CPOE orders is at our target of 90% and the percent for all other orders is at 60% but has decreased over the last 3 years. Education is being conducted to increase the CPOE rate for all orders across all services and Institutes.	X

*Healthcare Information and Management Systems Society

Stage	Description	NIH CC/CRIS	Done
3	<p>Clinical documentation installed (e.g. vital signs, flow sheets, nursing notes, care plan charting, and/or electronic medication administration record (eMAR) system are scored with extra points and are implemented and integrated with the CDR for at least one service in the hospital.</p> <p>First Level of clinician decision support is implemented to conduct error checking with order entry (i.e. drug/drug, drug/food, drug/lab, conflict checking normally found in the pharmacy).</p> <p>Some level of medical image access form picture archive and communication systems (PACS) is available for access by physicians via the organization's intranet or other secure networks.</p>	<p>Clinical documentation is used for prescriber and RN electronic documentation. The eMAR is used for documenting all medications administered in inpatient units, day hospitals and outpatient clinics.</p> <p>First level clinical decision is implemented for order checking in the forms drug/drug, drug/allergy, height/weight checks, pharmacogenomics, and protocol exclusions.</p> <p>PACS is installed and is available to clinicians through the CRC/CC with a link from results within CRIS and via CITRIX.</p>	X
2	<p>Major ancillary systems feed to clinical data repository (CDR) that provides physician access for retrieving and reviewing results.</p> <p>CDR contains a controlled medical vocabulary (CMV) and the clinical decision support system and rules engine for rudimentary conflict checking.</p> <p>Optional for extra points, Information from document imaging systems may be linked to the CDR.</p>	<p>The following systems have been implemented: Laboratory Information system (LIS) which includes lab, microbiology, anatomic pathology, transfusion medicine; Radiology Information System (RIS); Pharmacy Information System which include Sunrise Pharmacy and linkage to Omnicell medication stations with order profiling turned on; EKG/ECG system, SoftMed Transcription System; Theradoc Epidemiology System; Nutrition CBORD; Surgical Scheduling; Appointment Scheduling all interfaced with CRIS. Figure 3-2 reviews all the systems currently interfaced with CRIS and those planned. A link to the scanned medical record for historical and retired patients as well as a link to documents created outside has recently been implemented.</p>	X
1	Laboratory, pharmacy and radiology installed.	Laboratory, pharmacy and radiology installed.	X
0	<p>Some clinical automation may exist.</p> <p>Laboratory and/or pharmacy and/or radiology not installed.</p>		0

*Healthcare Information and Management Systems Society

Meaningful Use

The American Recovery and Reinvestment Act authorized the Centers for Medicare & Medicaid Services (CMS) to provide incentives for physician and hospital providers to provide “meaningful use” of an electronic health record (EHR). These incentive payments started in 2011. In 2015, providers are expected to have adopted EHRs and meet “meaningful use” or face financial penalties under Medicare.

While the NIH CC is not eligible to receive incentive payments from CMS for meeting EHR Meaningful Use standards put forth by the Office of the National Coordinator for Health Information Technology (ONC), CRIS does meet all requirements with the exception of creating and testing the capability to exchange key clinical information among providers of care and patient authorized entities electronically. The data contained within the CRIS database is deemed “research” focused with limited priority on the electronic sharing of the data with outside entities. The other exception is that the current patient problem list does not use a standard terminology. Problem lists are maintained electronically on all patients, but the use of SNOMED CT terms or terms that map to SNOMED is not used. Many treatments and diagnoses at the NIH CC have not yet been discovered or are in the process of being studied making it sometimes difficult to attribute a standardized term. A project is under way to implement a software application (IMO) that will provide clinical terms within CRIS that map to SNOMED terms. These clinically worded problems will be embedded into CRIS’ clinical documents for use by prescribers when caring for conventional clinical problems that our patients possess.

Table 3-4 Reviews the meaningful use criteria and reviews the NIH CC Status for each item.

Table 3-4. Meaningful Use Criteria

#	Measure Title	Stage 1 Description	Stage 2 Description	CC Status	Stage 1 Goal	Stage 2 Goal	Menu to Core
1	CPOE	Computerized physician order entry (CPOE) for > 30% of unique patient with at least one medication in their medication list	Use computerized provider order entry (CPOE) for medications, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter order into the medical record per state, local, and professional guidelines to create the first record of the order.	The original EHR referred to MIS was in the 90% for CPOE orders. Currently though for 2011, 87.9% of medication orders based on 37,090 total orders and 65.7% all orders out of 154,545. 2012 there was 90.9% medication order out of 34,710 and 62.3% of a total 174,870 orders. Then 2012 to date totals are 90.4% of medication order out of 32,976 and 61.2% out of a total of 178,692. The total number of orders has increased with the number of medication orders decreasing. The total percent for medication CPOE orders is at our target of 90% and the percent for all other orders is at 60% but has decreased over the last 3 years.	>30%	>60%	Core MU1
2	Drug-drug and drug-allergy CDS	Implement drug-drug and drug-allergy interaction checks.		Since 9/1/1981	Yes	Yes	Core MU1
3	Problem List and Diagnosis	Maintain an up-to-date problem list of current and active diagnoses.		As of 9/1/2009, a tab showing all diagnosis entered into 3M SoftMed is displayed to the all CRIS users. Problem list are stored in various clinical documentation notes. A review of an efficient solution is being conducted.	Yes	Yes	Core MU1
4	eRx	E Prescribing for >40% of the permissible scripts for patients for whom the EHR was used		All medications are prescribed in the EHR. All outpatient medications filled within the CC are electronically interfaced to the Outpatient Pharmacy system ScriptPro. All items to be filled outside are printed as a prescription. Those prescriptions filled outside are currently not sent out electronically.	>40%	>65%	Core MU1
5	Active Medication List	Maintain active medication list.		Since 9/1/2009	Yes	Yes	Core MU1
6	Medication Allergy List	Maintain active medication allergy list.		Since 9/1/1981	Yes	Yes	Core MU1
7	Demographics	Record demographics as structured data on >50% of all patients seen: preferred language, gender, race, ethnicity, DOB		Since 9/1/1981	>50%	>80%	Core MU1
8	Vital Signs	>50% of all patients age 2 and above seen with the EHR have vital signs (heights, weights, and blood pressure) recorded as structure data. Calculate and display body mass index (BMI). Plot and display growth charts for children 2–20 years, including BMI.		Since 9/1/1981	>50%	>80%	Core MU1

#	Measure Title	Stage 1 Description	Stage 2 Description	CC Status	Stage 1 Goal	Stage 2 Goal	Menu to Core
9	Smoking Status	Record >50% of patients smoking status for patients 13 years or older seen with the EHR.		Since 3/9/2006. Included in Inpatient Clinical Documentation including Admission Assessment.	>50%	>80%	Core MU1
10	Clinical Quality Measures	Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.		This issue is “not applicable” for the NIH CC as we do not report any data to CMS as we do not bill for CMS funds. We report ORYX data to the Joint Commission as part of our accreditation activities.	Yes	Yes	Core MU1
11	Clinical Decision Support Rule	Implement one clinical decision support rule	Implement 5 clinical decisions support interventions plus drug/drug and drug/allergy	CDS in the form of alerts is implemented for order checking for height/weight changes, pharmacogenomics, drug tapering and protocol exclusions as part of order entry. Protocol order sets and guided dose algorithms based on weight and body surface area (BSA) are available as well as references for medication ordering are provided within CRIS.	Yes -1	Yes – 5	Core MU1
12	Patient Portal	> 10% of applicable patient seen are provided with timely electronic access (within four business days) to their health record.	Provide online access to health information for more than 50% with more than 10% actually accessing.	Implemented July 2013. As of August 26, 2013 over 3,000 accounts.	>10%	>50% with 10% usage	Menu MU1
13	Clinical Visit Summary	Provide > 50% of patient seen with the EHR a clinical summary within 3 business days	Provide clinical summaries for patients within 24 hours for each office visit	Currently send discharge documentation to all inpatients within 3 days of discharge and for all first time outpatients.	50% within 3 days	50% within 24 hours	Menu MU1 Core MU2
14	Security Risk Analysis	Ensure adequate privacy and security protections for personal health information. Conduct or review a security risk analysis and implement security updates as necessary and correct identified security deficiencies.	Conduct or review security analysis and incorporate in risk management process.	S&A conducted every three years with annual review. HIPAA review will be conducted between 9/1/2013 – 1/31/2014.	Yes	Yes	Menu MU1 Core MU2
15	Drug Formulary Checks	Implement Drug Formulary Checks		When we build items in CRIS we only build formulary items in the general browse—aside from some of our investigational agents. A list of formulary medications is available through the pharmacy intranet site which can be accessed through CRIS. There is a formal process to add items to the formulary and to review the formulary annually.	Yes	Yes	Menu MU1 Core MU2
16	Lab Results saved as Structured Data	>40% of clinical lab test results are stored as structured data for patients seen with the EHR		Since 9/1/1981	>40%	>55%	Menu MU1 Core MU2
17	List of Patients by	Generate at least one report of patient by		As of 9/1/2013 provide lists by Protocol Number	Yes	Yes	Menu

#	Measure Title	Stage 1 Description	Stage 2 Description	CC Status	Stage 1 Goal	Stage 2 Goal	Menu to Core
	Condition	specific conditions to use for quality improvement, reduction of disparities, research or outreach		within CRIS.			MU1 Core MU2
18	Patient Reminders	>20% of all unique patients 65 years or older or 5 years old or younger with the EHR were sent an appropriate reminder per preventative/follow-up care	Requires the use of the EHR to identify appropriate reminders instead of just sending reminders based on patient preference	Reminders are sent based on scheduled appointments. Preventative/follow-up care would not apply.		Yes	Menu MU1 Core MU2
19	Education Resources	>10% of all patient seen are provided patient specific education resources through the use of EHR technology		Scheduled to be added to the portal in calendar year 2014.	>10%	>10%	Menu MU1 Core MU2
20	Medication Reconciliation	Performs medication reconciliation on >50% of transitions of care or relevant encounters for EHR patients		Currently an electronic and manual process resulting in the review of a paper report with signature filed in the medical record.	>50%	>65%	Menu MU1 Core MU2
21	Summary of Care for other Providers	EP who transitions or refers the patient seen with the EHR to another setting of care will provide a summary of care record for >50% of transitions and referrals.	Provide summary of care document for more than 65% of transitions of care and referrals with 10% sent electronically	Reviewing Referring Portal for calendar year 2014.	>50%	>65% with 10% electronically	Menu MU1 Core MU2
22	Immunization Registry	Perform at least one test of certified EHR technology's capability to submit electronic data to immunization registry/systems	Measured through successful ongoing submission.	Reviewing alternatives for calendar year 2014.	Yes	Yes	Menu MU1 Core MU2
23	Surveillance Data	Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.		Reviewing alternatives.			Menu MU1 Core MU2

Figure 3-3- CRIS Chemotherapy Order Set

Order sets are built to support provider order entry per research protocol. They are structured so that the appropriate orders specified within the protocol can be efficiently entered with appropriate information, providing efficiency and reliability to the care provider.

Medications - TEST, PATIENT LAB INPATIENT 1

TEST, PATIENT LAB INPATIENT 1 39-81-76-9 / 090302200368 77y (07/18/1935) Female

CC-CADRE Ognibene, Frederick

Allergies: acetaminophen, Fortaz, Other, Alcohol, Wine, Cheese

11-C-0123 Arm 1 Medications, OSF [41 orders of 44 are selected]

Allocate Order to Protocol

Height/Weight/BSA/BMI
 Height (cm) 171 Weight (kg) 68 BSA 1.8 BMI 23.3
 01/11/2013 11:31 01/11/2013 11:31

Protocol Information:
 If patient is obese (BMI>35), use practical body weight to calculate dosage of cyclophosphamide, mesna, and fludarabine. Practical weight = average of actual weight and ideal weight.
 ONDANSETRON dose = 0.15 mg/kg rounded to the nearest even mg (min = 8 mg; max = 16 mg)
 ANTIEMETIC: Select EITHER prochlorperazine OR promethazine - DO NOT order both concurrently.
 SULFA ALLERGY: If pt is allergic to sulfa, contact Research Nurse to schedule Pentamidine treatments.

Enter Date for Day -7:

Ordering Instructions:
 Select check box for medication to be ordered. Complete all appropriate information. Scroll right for additional fields. To open order form for editing, click on medication name. To view entire contents of a truncated field, hover over field.

Preparative Regimen, Day -7

Medication	Strength	Dose	Calc Dose	UOM	Additives	Base Solution	Route	Route Modifier	Infuse
Chemo Hydration - 1 item(s)									
<input checked="" type="checkbox"/> 0.9% Sodium Chloride Inj		1,000		mL	Potassium Chloride Inj 10 mEq		by intravenous infusion		
Pre-Cell Infusion Chemo - 7 item(s)									
<input checked="" type="checkbox"/> Furosemide Inj	10 mg/mL		20	mg			by intravenous push		
<input checked="" type="checkbox"/> Ondansetron Infusion			10.2	mg		5% Dextrose Inj 25 mL	by intravenous infusion		15 min
<input checked="" type="checkbox"/> CycloPHOSphamide Infusion			4,080	mg		5% Dextrose Inj 250 mL	by intravenous infusion		60 min
<input checked="" type="checkbox"/> Mesna Infusion			1,020	mg		0.9% Sodium Chloride Inj 100 mL	by intravenous infusion		60 min
<input checked="" type="checkbox"/> Mesna Infusion			4,690	mg		ium Chloride Inj 500 mL	by intravenous infusion		23 hours
<input checked="" type="checkbox"/> Furosemide Inj	10 mg/mL		20	mg			by intravenous push		
<input checked="" type="checkbox"/> Fludarabine Infusion			45	mg		0.9% Sodium Chloride Inj 100 mL	by intravenous infusion		30 min

Day -1

Medication	Strength	Dose	Calc Dose	UOM	Additives	Base Solution	Route	Route Modifier	Infuse Dv
------------	----------	------	-----------	-----	-----------	---------------	-------	----------------	-----------

Drug Info

OK Cancel

Figure 3-4. CRIS Pharmacogenomics Ordering Example

Pharmacogenomics order sets provide clinical decision support and pull relevant clinical information into the same form, providing a structured methodology for care providers to order and review required lab results before administering specific medications.

A = Message box for clinical information

B = Message box for override reason description
The Override Reason Number field is required based on the patient case

C = Message box where PG test result information is displayed

D = Grid for ordering PG tests These are automatically pre-selected depending on the case

E = Grid where medications can be ordered

Carbamazepine tablet [1 orders of 2 are selected]

[Allocate Order to Protocol:](#)

A Serious dermatologic reactions, including Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome, have been reported with carbamazepine treatment. Greater than 90% of reactions occur within two to three months of treatment. Testing for HLA-A*3101 and HLA-B*1502 is recommended to assess risk.

HLA Genotype Test Override Reasons:

B 1. Patient currently receiving medication without reaction.
2. Outside HLA genotype test result is negative and documented in CRIS.
3. Clinical justification documented in CRIS.

Date of Last HLA Test at NIH:

C No Orders have been placed at NIH.

HLA Genotype Test:

Height/Weight/BSA/BMI:

Height (cm)	Weight (kg)	BSA	BMI
<input type="text"/>	<input type="text"/>		

Override Reason Number:

	This order will be protected, if an order was previously placed at NIH.	Priority:	Reason for Stat/Priority Precedence:	Requested Date:	Testing Category:	Special Instructions:	Prescribed Edit:
<input checked="" type="checkbox"/>	Sequenced Based HLA-A,B	Routine		07/02/2013	General		

D Ordering Instructions:
Select check box for medication to be ordered. Complete all appropriate information. To open order form for editing, click on medication name. Scroll right for additional fields.

To complete the Take Home sections, be sure to have selected the Take Home Session Type.

Tablet/Capsules:

Medication Name:	Strength	Dose:	UOM:	Frequency:	Route:	Route Modifier:	Use Own
<input type="checkbox"/> Carbamazepine	200 mg tablet	200	mg	every 12 hours	by mouth		

E

Figure 3-5. CRIS PDF Result of Advanced Cardiovascular Imaging

Multiple documents generated from ancillary systems are included in CRIS and accessible through a linking and viewing mechanism for the care provider. These documents include Cardiovascular Imaging, National Eye Institute documentation, signed patient consents, and bronchoscopy and endoscopy procedure documents from the Provation information system, among others.

Cardiac CT

3 / 7 82.2% Find

MEDICAL RECORD		CARDIAC CT	
NHLBI Advanced Cardiovascular Imaging Laboratory; National Institutes of Health			
Exam Date:		Exam #:	
Coronary Angiography:			
Vessel Segment	Stenosis	Plaque Type	
LEFT MAIN-5			
5 Left Main	<30%	Non-calcified	
LAD (worst lesion)			
6 Prox	>=70%	Non-calcified	
7 Mid	normal	N/A	
8 Distal	normal	N/A	
9 Diag1	>=70%	Non-calcified	
10 Diag2	normal	N/A	
LCX (worst lesion)			
11 Prox	normal	N/A	
12 OM1	50-69%	N/A	
13 Distal	normal	Non-calcified	
14 OM2	normal	N/A	
15 PDA	<30%	Non-calcified	
17 RAMUS	N/A	N/A	
RCA (worst lesion)			
1 Prox	occluded	Non-calcified	

Figure 3-6. CRIS Access to PACS

CRIS offers multiple pathways for providers to access a patient's PACS images, either through a link available at the patient result level, at the patient level with context sharing between CRIS and PACS, or through a separate application which can be invoked through CRIS.

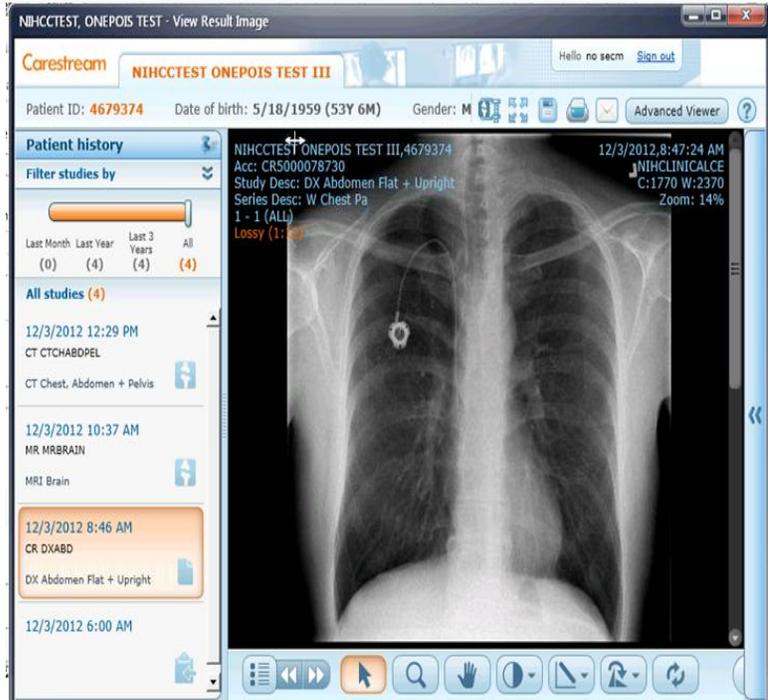
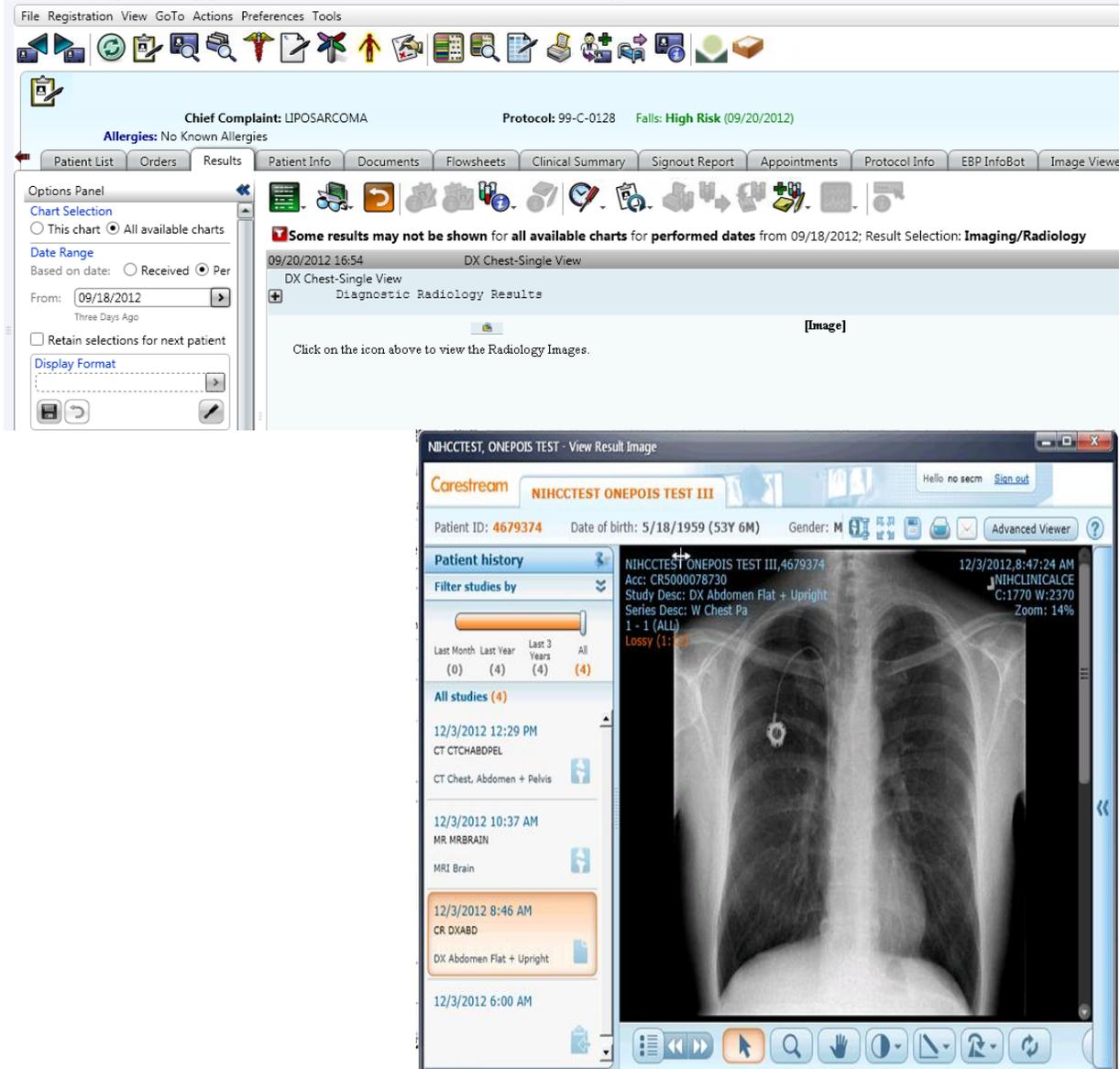
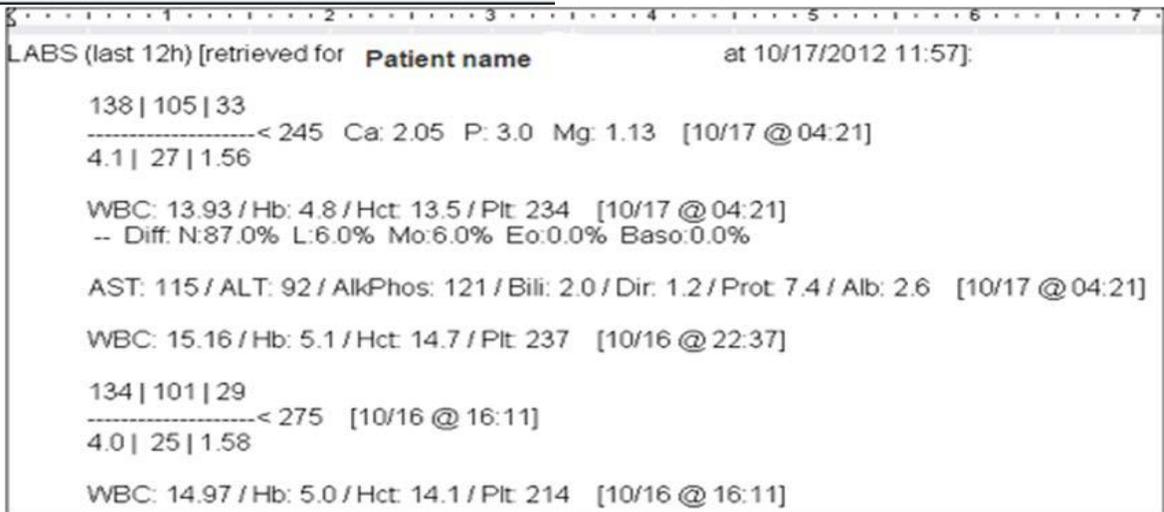
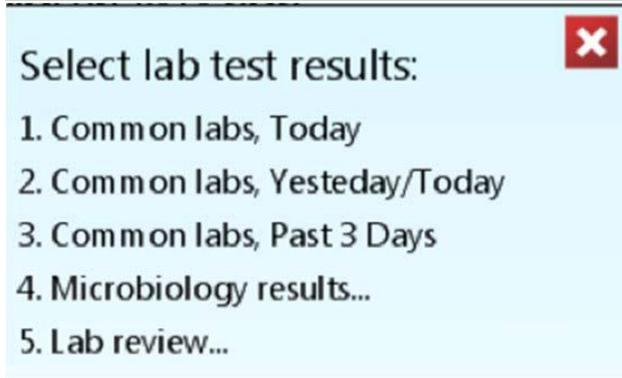
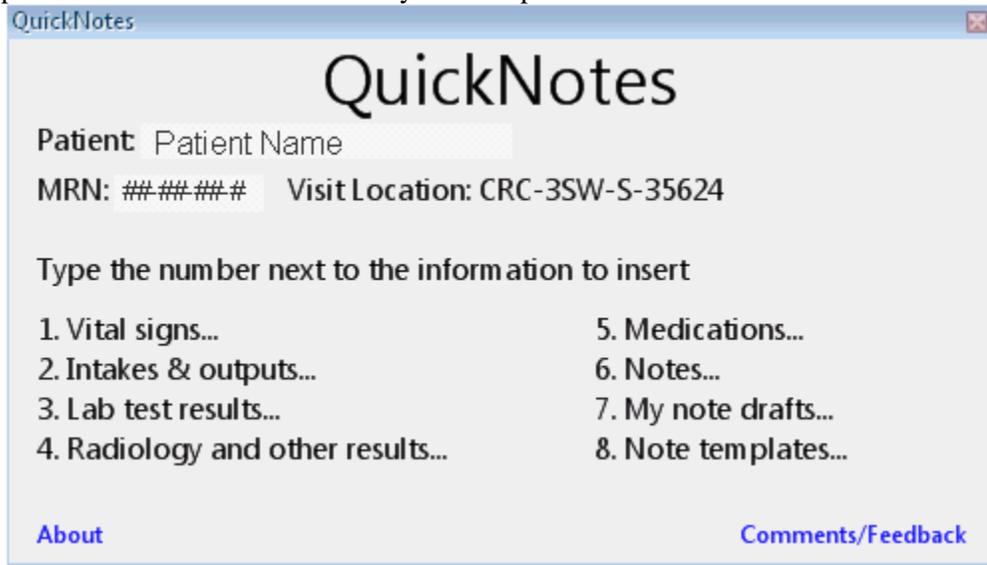


Figure 3-7. CRIS Creation of QuickNotes

QuickNotes is a tool which increases the efficiency of care provider documentation by allowing the user to select among common data elements within the patient record to pull in relevant clinical data for the patient which can then be edited by the care provider and stored in Clinical Documentation.



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SECTION 3

RESEARCH SUPPORT

CRIS/Sunrise Acute Care

Many acute care organizations perform clinical research in addition to their patient care mission. At the NIH Clinical Center, conducting research is the primary mission. Our challenge has been to support clinical research using a commercial off the shelf product (Allscripts Sunrise Acute Care) developed with a strong clinical care focus rather than one designed to support research. To address the research requirements of our clinicians and support staff, we were required to customize multiple clinical components of the research process into our system and deliver administrative data regarding volume of protocol use and resource utilization per protocol. Below are examples of these essential research components with brief explanations of their configuration.

- All patients at the NIH CC are admitted on a research protocol study and many are enrolled in more than one. With over 1,500 active protocols, it is important that all system users are able to identify the protocols on which the patient is currently enrolled. We were able to achieve this by utilizing system functionality intended to manage a patient problem list (Health Issues).
- Additionally, we developed a method to attribute medical orders placed in our CPOE system to a specific protocol. With each order associated to a designated protocol, data is transformed into information regarding protocol resource utilization.
- To further support clinical research, a “Protocol Tab” was developed to display a listing of all protocols in which the selected patient is enrolled along with links to informational resources, including the original working protocol documentation and associated research literature via PubMed. The scanned (pdf) signed protocol consent is also available via a link contained in the Protocol Tab.
- The development of protocol order sets is another essential component configured into our system to support research. We currently have 3,444 protocol order sets available for investigators to enter orders that reflect the correct sequence and timing of the orders to ensure that the protocol is carefully followed. When appropriate, default values are pre-entered to reduce the need for manual entry and the possibility of error. Investigational medications contained within these order sets are configured to allow only those physicians approved to place these types of orders. This application security configuration has proven to require a significant amount of maintenance, yet is mandatory from a regulatory agency perspective.
- To support clinical documentation of research activities, we have developed multiple structured notes and flow sheets for care providers to enter data elements needed to capture the results of research treatment and outcomes. To pull all these elements together, protocol based data extractions are electronically transmitted to researchers on a daily basis to support automated data transfer to other Institute databases.

We came to the conclusion that a clinical information system that completely supports research does not exist. The customization of a clinically focused system to capture research activities became the goal of our efforts. We feel that our significant success with protocol orders sets and with attribution of all medical orders to specific protocols is in large part a credit to our standardization efforts. This data can be easily manipulated, aggregated, and analyzed by both researchers and the Clinical Center administration. While our clinical documentation has yet to achieve this degree of standardization and utility, both the goal and the payoff of protocol management appear increasingly evident.

Other Systems/Departments that Support Research

ProTrak is a protocol tracking system used to maintain meta information around the protocol study itself, following the protocol through the Investigational Review Board (IRB) process from planning of the protocol until it is approved by the IRB. Protocols are assigned an accrual status which reflects where they fall in the protocol life cycle, and which are used for making those protocols available for attribution within CRIS. The system tracks all the relevant dates and demographics of a protocol.

Patient Recruitment Applications support the recruitment process from the first call from a potential protocol participant until the participant is assigned to a protocol as a CC Patient. The application includes a contact management component to track calls from potential protocol participants, a protocol management component to evaluate a caller's eligibility criteria for protocols that are actively seeking patients, and an advertisement component to track the effectiveness of an advertisement. In addition, these applications include a payment component to compensate volunteers.

Patient PCs

Since patients freely give their time to participate in protocols, it is important to provide an environment which encourages the patients to want to stay and participate. To provide such an atmosphere, we provide PCs in all of the inpatient rooms to allow patients access to the internet and their home email accounts. Using the Patient PCs, patients will be able to access the CC Patient Portal which allows patients to view their test results.

Patient Portal

A patient portal which is integrated with CRIS now allows the patients to access portions of their electronic medical record remotely, viewing specific demographics, clinical documents and results. Future plans include enabling Electronic Health Messaging between patient and provider, providing information on a patient's scheduled appointments, and providing additional information around a patient's active medications.

Information Technology Center (ITC)

The ITC provides NIH researchers with the latest technologies to create presentations and posters for various research symposiums at NIH. The biggest clientele is the Student Intern Programs which occur throughout the year.

Clinical Informatics: Outcomes and Evaluation

Throughout its organizational life, the Department of Clinical Research Informatics (DCRI) has implemented, integrated, and deployed a significant number of clinical information systems and has completed numerous upgrades to those systems both in clinical features and technology, all the while striving to improve functionality, usability and overall system quality. With the increased recognition of the many priorities associated with clinical information systems and the significant investments required, one might ask, "how do you measure the success of an implementation?" First, we must acknowledge the requirement of developing and implementing strategies to assess and confirm that improvements have been made. The goal is to seamlessly integrate the evaluation of outcomes measures into project planning and workflow so that it becomes an adopted and embraced systemic process.

To achieve this goal, DCRI has organized a collaborative group comprised of both internal and external stakeholders to work on developing standard evaluation methodologies to measure quality, effectiveness, and overall success of our clinical information system implementations and system and technology improvements. The outcomes of these evaluations are documented and disseminated amongst key stakeholders and the health information technology community as appropriate. The information gained

will help to measure ongoing improvements in the quality of business processes and patient care at the NIH Clinical Center and serve as a guide for prioritization of future efforts and investments.

This is achieved through an Informatics Outcomes and Evaluation initiative, the goals of which are to develop a standardized and repeatable evaluation methodology to measure the effectiveness and outcomes of clinical information technology at the NIH Clinical Center and integrate that methodology into the DCRI implementation processes. Indicators identified as significant outcome measures to evaluate have been adopted from the Agency for Healthcare Research and Quality (AHRQ) Health Information Technology Evaluation Toolkit (2009) and include:

- Clinical Outcomes Measures
- Clinical Process Measures
- Provider Adoption and Attitudes Measures
- Patient Knowledge and Attitudes Measures
- Workflow Impact Measures
- Financial Impact Measures

Appropriate metrics are identified and analyzed for evaluation projects to help guide system design, acquisition, and development and set organizational priorities. This provides the potential to improve the quality and safety of patient care and to streamline business processes, reducing costs and improving productivity and satisfaction. The Outcomes and Evaluation group partners with the Project Management Office (PMO) and various other inter- and intra- departmental colleagues to identify projects and initiatives to be evaluated. A multidisciplinary collaborative process has been implemented to determine and prioritize the outcomes measurement and evaluation project list using an assessment process that includes assigning a priority and complexity score for proposed evaluation projects.

The Informatics Outcomes and Evaluation group has successfully evaluated 1) The effectiveness of an alert to stop users from entering inaccurate heights and weights; 2) The frequency and quality of progress notes that have been copied from previous electronic entries; 3) The cost savings from implementing an electronic cumulative lab summary; 4) The effectiveness of obtaining quality user feedback via an electronic suggestion box embedded in a clinical system; 5) The effectiveness of a paper Critical Care Nursing Flow sheet in comparison to an electronic spreadsheet to compare the computational data for a patients' 24 hour intake and output; 6) 30 retrospective anesthesia intraoperative paper records to evaluate for pre-defined documentation requirements; and 7) The Signature Manager medical logic module (MLM). The outcomes of these evaluations are documented using a hybrid approach adopted from AHRQ standards and the guidelines from STARE-HI (Statement on the Reporting of Evaluation studies in Health Informatics) (Ammenwerth, et al., 2009).

The most recent outcomes project involves the evaluation of documentation types that are in CRIS, but are not being used for documentation by users. The outcome may be to assess whether to make these document types unavailable for selection, which would potentially make it easier for users to locate relevant documents and information in the system or to educate users on the availability of these notes and the purpose of these notes.

The Informatics Outcomes and Evaluation is in the process of selecting Clinical Decision Support (CDS) alerts within CRIS to evaluate effectiveness. The objective of CDS is to provide the right information, to the right person (physician, nurse, pharmacist, and technician), in the right intervention format (alert, order set, clinical information), in the right channel (user screen, email message, text to a mobile device), at the right time in the workflow to aid in making healthcare decisions (HIMSS, 2009) & (Osheroff JA,

2007). Within CRIS Sunrise one way in which we incorporate CDS is through Medical Logic Modules (MLMs). The group will review the duplicate order checking MLM which was implemented early 2013 to alert providers of the presence of potentially duplicate repeat lab orders.

This Informatics Outcomes and Evaluation initiative holds the promise of guiding technological progress and investment in clinical information systems well into the future, optimizing resource use and providing real information on the outcomes associated with clinical system implementations and returns on the investments made in them.

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SECTION 4

IT LEADERSHIP PHILOSOPHY/CHALLENGES

Challenges

For several years, the NIH Clinical Center has been operating in an environment of constrained budgets. Concurrently, the DCRI operates within an environment where there are a growing number of new initiative demanded by CC and IC leadership and stakeholders, and these constrained budget is unable to support critical staffing needs. Additionally, pay raises, bonuses and cash awards have been frozen. Finally, travel and training restrictions are continuously being pressed upon DCRI and the CC as a whole. Taking all of these factors into account, DCRI is in a difficult position where it must maintain, if not exceed, the quality and breadth of its current operations and projects without having the necessary resources to make it possible. This reality weighs heavily on both DCRI leadership and staff. Since the last operational review, the future outlook for DCRI's ability to remain cutting edge in their approach to the provision of technological solutions that can best serve the clinical research mission of the NIH IC's is in serious jeopardy. Despite these challenges, the DCRI continues to strive toward excellence, and employ innovative approaches to leverage their limited resources to remain a proactive collaborator and partner with many CC and IC stakeholders, to enable them to continue support of critical projects and initiatives to improve patient care and research.

DCRI Improvement

To improve the department as a whole the department underwent an operational review in 2009. The leadership items listed below is addressed in Section 7: under IT Governance with a review of the Information Technical Advisory Group as well as in Section 11 Key IT Drivers and Influences which contains a review of the CRIS Prescriber and Clinical Documentation Group and Outreach Activities performed by DCRI.

- The CC Director should create a multi-stakeholder governance entity, through which a guiding set of principles can be applied to all IT activities.
- The CC should work to reduce the number of competing committees that incompletely contribute to IT decisions.
- DCRI should develop mechanisms that will facilitate working more closely with clinicians to understand and serve their IT needs.

The Quality of Service and Resource Infrastructure recommendations are reviewed in this Section as well as in Section 7: Management Controls, Section 9 System Controls and Section 10: Quality of Service Metrics.

- DCRI must improve their collaboration with users, colleagues, and external experts.
- DCRI should explore opportunities to consolidate technology infrastructure to improve service and reduce costs
- DCRI should identify clinician/investigator leadership to assist them to drive innovation.
- DCRI should work to implement a comprehensive business continuity and disaster recovery plan.
- DCRI must work to develop more useful performance metrics (Ex: System Change Requests, Security).
- DCRI should evaluate Service Level Agreements (SLAs) with internal CC and other Institute customers to ensure a comprehensive summary of services to be provided and quantitative measures of performance.

- Once an IT governance structure is implemented and projects begin to be prioritized, staffing levels should be reviewed to ensure alignment with governance goals.

For the Training Recommendations regarding CRIS users, DCRI moved to an online training platform for Physicians in 2009. Additional outreach activities to provide training opportunities and road shows and rounds across departments are reviewed in Section 11: Key IT Drivers and Influences as part of the Outreach Activities. DCRI staff participates in multiple opportunities to share with Allscripts and Healthcare forums at Round Tables, User Conferences and online with presentations provided by DCRI Staff under Section 6: Staffing under Staff Accomplishments. The end of Section 6 reviews the training opportunities provided to DCRI Staff.

- The Clinical Center should mandate on-line training as an augmentation to limited classroom training.
- DCRI should explore partnerships with other Eclipsys sites to exploit existing training solutions.
- The CIO should ensure that a standard role-based training curriculum is developed for all staff and ensure execution.
- DCRI should involve clinical and research users in the development of training material.

The “CIO Story”

There is a conversation based on a sermon that was repeated from time to time and shared when new people joined DCRI. The sermon goes as follows: A reporter is covering the building of a church. She goes to the church and starts to interview those working on the building of the church. The reporter is interviewing multiple people involved in building the church asking them “What is your role?”. She talks to the plumber who states that without him there would be no church. The plumber explains that water is needed for the bathrooms, the kitchen, most importantly, for baptisms. The reporter then talks to the electrician. The electrician states that without her there would not be a church. “We need electricity for heat, cooling, and light, and of course there needs to light”, she says. The reporter asks the same question to which the person sweeping the floor answers “Building a Church”.

The approach leadership takes is that we are a team and it takes all of DCRI working with each business unit in the organization to provide IT services at the highest level. Everyone in the department and every task is important. Working together is how we will accomplish success.

Overarching guidelines were identified in 2012 to the management of DCRI. These include:

- Providing an environment in which staff can succeed: An environment in which they are trained, share in decisions, are respected and have a voice.
- Developing a culture of proactive management and monitoring of staff, systems and processes.
- Managing expectations through enhanced communication, education, and increased transparency.
- Focusing on efforts to consolidate, streamline, reorganize and clean-up current critical systems and functions.
- Applying lessons learned and best practices in the delivery of effective systems, i.e. get it right the first time.

Technical, Processes and CRIS/Research goals to be accomplished in the 2013/2014 timeframe were identified to meet the goals set for 2017. The definitions for these three categories are:

- **Technical** – Goals related to technical functions that ensure system stability, efficient monitoring, effective and reliable access and minimal system interruption.
- **Processes** – Goals related to processes that impact the use of technology at the Clinical Center.
- **CRIS/Research Systems** – Goals related to improvement activities for our various clinical systems that will lead to enhanced patient care, increased user satisfaction, and support of research.

The technical goals for 2013/2014 are:

- To develop future technical architecture plan based on best practices and lessons learned.
- To document current system and data flows to capture the evolving complexity of the CC's clinical systems.
- To implement concurrent monitoring methodologies.
- To maintain 99.9% system uptime across systems.
- To maintain a Level 3 data center.

The process goals for 2013/2014 are:

- Identify and implement new model of desktop support to increase same day resolution by the Tier I support team.
- To develop enhanced training program for DCRI staff to ensure consistent and current system knowledge, as well as back-up support.
- To implement methods to improve transitioning of systems from implementation to operations & maintenance.
- To increase dependency between the initiations of IT project work and priority setting with the IT Advisory Group (ITAG).
- To create improved processes to provide efficient development and management of protocol order sets.
- To continue regularly scheduled CRIS user group interactions.
- To maintain a secure system that meets CC business processes and HHS/NIH security requirements.

The CRIS/Research System goals for 2013/2014 are:

- To provide a fully integrated clinical research informatics environment, and reach Phase 7 HIMSS Analytics.
- To provide patients and referring physicians an electronic and real-time access to their health information.
- To maintain a comprehensive enterprise architecture that will ensure flexibility, high availability, stability of operations and security over patient records.
- To provide innovative solutions to ensure outstanding support of clinical care, patient safety, regulatory compliance, and clinical research.
- To deliver outstanding customer service to our staff, institute staff and patients.

Changing the Internal DCRI Culture

The Gartner Infrastructure and Operations Maturity Model (IOMM) evaluate six attributes: (1) Organizational structure; (2) Roles; (3) Culture; (4) Skills; (5) Training; and (6) Metrics. As advances are made in maturity, new roles are added, moving from a technology-centric focus in Level 1 to a process orientation in Levels 2 and 3 and a relationship manager focus in Level 4. In Level 5 — business partnership — the relationship manager (and other roles, such as CTO) drive business innovation and competitiveness. Just as the roles advance, so does the organizational structure, which begins with technology centrality and moves to hierarchical and then to process orientation (with heavy reliance on matrix management) and service centrality in Level 4. Level 5 has little formal emphasis on the organizational structure, because a high degree of business credibility and trust has been achieved, and the organization moves toward informal and virtual structures to drive business innovation.

The cultural aspects of maturity advance significantly at each level, with those at Level 2 trying to stamp out the hero culture and, instead, reward individuals and teams to become proactive rather than reactive. As a result, they begin to look at industry best practices, but it is not until Level 3 that the best practices have a formalized focus and investment. By Level 4, the best practices are effectively used

with benchmarking as a means of measurement. By Level 5, the organization is leading the charge to develop industry best practices. Similar progressions are made in skills, training and metrics as maturity is advanced.

From 1995 – 2002 DCRI was at Level 1 and this progressed in 2002 – 2004 to Level 2. From 2004 to 2010 we were at low to mid Level 3. From 2010 to present state we were at the high end of Level 3 working towards a Level 4.

Table 4-1. Gartner Infrastructure and Operations Maturity Model (IOMM)

Level	Organization	Roles	Culture	Skills	Training	Metrics
0	None	None	Inconsistent	None	None	None
1	Aligned by Technology	Technology Specialists	Hero-Oriented	Job Titles in Place	Limited — Technical	FTE per Tech. Area
2	Hierarchical Org.	Process Roles Emerge	Looking at Best Practices	Job Levels Defined	Technology; Limited — Process	Staff Utilization
3	Process-Centric; Matrix Mgmt.	Process Owner Role Well-Defined	Working on Best Practices	Employee Skills Tracked	Formal Training Policy; Job Rotations	Staffing Ratios and Productivity
4	Service-Centric	Relationship Mgr. Role Well-Defined	Best Practices Effectively Used	Actively Manage Skills Portfolio	Customer Service Training; Mentoring	Staff Retention; Service Quality Goals
5	Little Focus on Formal Org. Chart	Relationship Mgr. Drives Innovation	Developer of Industry Best Practices	Effective Sourcing of Skills	Business & Industry Training	Business-Integrated Metrics

(Gartner Summit Events as presented by Ed Holub).

Three growth areas within our department that have allowed us to navigate from Level 2 to Level 4 are portfolio management, project management and configuration management. All projects utilize our project management structure, and we have used this structure beyond project management. As part of the CRIS Sunrise 26 hour down in May, 2010 we used existing project management checklists to guide us through the restoration process of the database and CRIS Sunrise. Checklists were used throughout the down, with the project management team coordinating each of the necessary tasks. A debrief of the events concluded with multiple lessons learned sessions. The success of this methodology is also evidenced by the fact that staff request that we follow the project management methodology for every task that we perform, no matter how large or small. The staff in the department routinely keeps each other accountable on whether or not configuration management was followed successfully. Portfolio management, project management and configuration management have become engrained in the culture of our department.

To build on best practices, we work to leverage the portfolio, project and configuration management processes. When we realized that our security reviews were being conducted too late in the process to make changes, we added those tasks to the project management process at the time of planning. When we realized that our infrastructure was getting too complex, and we found ourselves adding systems and technology at a rate too fast to manage successfully, we added architecture reviews with the documentation of the infrastructure as part of the project lifecycle. As a result we are able to address

security and architecture concerns early in the process, thereby reducing unnecessary rework and system complexity.

A review of an IT project showing how the project management process has been adapted and leveraged to meet the ever changing needs is provided in the next section: The implementation of the NAS. The documentation supporting the NAS project is in Appendix A. An additional example reviewing the implementation of CRIS Sunrise/SCM 5.5 is available in Appendix B and C.

APPLYING THE LEADERSHIP PHILOSOPHY: THE IMPLEMENTATION OF THE NETWORK-ATTACHED STORAGE (NAS) CC FILESERVER

Project Description

For many years, the Clinical Center's shared file system was reliant on a home-grown solution called "Sapphire." Over time, the demand for additional space, secure data storage and access, and fast, 24/7 data availability began to take a toll on the existing infrastructure. In the remaining months prior to its replacement, Sapphire's nearly 3,000 user directories and 177 group shares suffered from almost-routine downtime and performance issues. The DCRI Enterprise Architecture team was called upon to make a recommendation on new equipment that would be able to handle the Clinical Center's storage needs now and far into the future.

The discussion and identification of a Network-Attached Storage (NAS) solution encompassed the initiation process of this project, and a DCRI project manager was assigned once procurement was complete and resources were ready to begin.

The scope included the following high level objectives:

- To install redundant NAS servers in building 10 (primary) and building 12 (failover);
- To develop and deploy an appropriate network infrastructure to handle the new NAS architecture;
- To train CC DCRI staff (and end users, as appropriate) on how to manage data in the new system;
- To migrate all existing Sapphire data to the NAS with minimal disruption;
- To place the resulting interface and configuration under the same Configuration Management process as CRIS.

Additionally, the project included the procurement of two critical pieces of software for management of the new storage system: A centralized anti-virus server and a quota management program.

How the project was managed during initiation

The initiating phase of the project began with the DCRI Technical Architect organizing a working group of Sapphire system administrators, IT supervisors, and interested stakeholders. The goal was to explore multiple storage options, discuss trade-off, examine leading technologies and present an actionable recommendation to the CIO.

The system administration team commenced EA discussions by advocating an upgrade to the existing Microsoft Window server's operating system. This solution assumed the front-runner position as staff's familiarity and experience in administering a high volume, professional, enterprise-wide Microsoft architecture reduced learning curves; increased confidence in installation, configuration, and troubleshooting; and minimized costs. The cons to this solution were a continued single point of failure and increased system admin workload during the build process.

A second advocated option was the implementation of a Microsoft Distributed File System infrastructure. This solution presented several advantages from the OS upgrade only, namely, increased fault tolerance,

increased availability, and increased scalability for future growth. However, EA group discussions found the solution's disadvantages included a new technology learning curve, purchase of both new hardware and software, educating users on new access paths, moderate to high workload to design, build and migrate, and possible incompatibilities with older Macintosh systems. The EA group felt these disadvantages were manageable but determined an examination of non-Microsoft vendor solutions were necessary to fully understand the introduction of new technology.

The EA group then scheduled presentations from leading storage vendors to determine the availability of different storage technologies, their maturity, and their applicability to solve a basic file server requirement. These presentations led to the consideration of a Network Attached Storage (NAS) infrastructure solution. The advantages to a NAS were a single turn-key solution, maintained by the vendor, and administered by the DCRI system administration staff. This allowed staff to focus on learning administration tasks and software management tools instead of focusing on hardware and software installation. The NAS solution provided high reliability, scalability, and fault tolerance in a mature proven storage technology. The primary disadvantage was educating users on a new access path. Finally, the EA group examined the "cloud" solution. The advantages to this solution are the elimination of system administration tasks, increased availability, increased scalability, vendor-supplied support, initial low cost of entry, and NIST/NSA certified data security compliance. The disadvantages were the unknown effect on systems requiring high-speed responsiveness, the side effects on CC disaster planning and continuity of operation plans, and the coordination required in addressing and resolving problems. The EA group concluded a test and pilot of cloud storage should precede any purchase decision. The EA team reported back its recommendation to the CIO for consideration and action in the form of an options document and briefing. The EA team's NAS recommendation was approved, and vendor selection initiated. As vendor selection must follow Federal Acquisition Regulations, a requirements documents and statement of work were drafted by the EA team and forwarded to the Procurement Office. An EA subcommittee consisting of system administrators and supervisors conducted vendor evaluation and selection. The goal was to allow the system administrators responsible for the eventual NAS management the ability to choose their system.

How the project was managed during planning

After a vendor selection was made and an order was placed, a PMO project manager was assigned. A project scope was created, and the vendor (NetApp) became engaged. NetApp provided a dedicated project manager and technical engineer that would assist with the creation of the NAS environment. The contract was for a fixed number of hours, which had to be carefully managed to ensure that vendor support would be available for the duration of the project.

On the whole, the project was divided into two segments: The installation and configuration of the NAS, and the migration of existing Sapphire shares to the new architecture.

At the project's kickoff, NetApp provided a "System Installation Workbook" – a 30-page technical document to be completed by the NIH CC to provide the vendor with sufficient information to ensure a seamless implementation before the engineer arrived on site. This document was reviewed during several initial meetings, and it was helpful to identify the outstanding questions and pre-requisites that had to be considered before equipment was installed. This document ultimately translated into an "As-Built" technical configuration guide that was completed at the end of the project.

After several review of the Installation Workbook, the NetApp technical engineer arrived on-site to help with the installation of the hardware in both buildings 10 and 12. The installation took 3 full working days, and although DCRI staff certainly had the skill set to install the servers, using time from the vendor to complete this process freed up the DCRI resources to allow them to concentrate on designing the architecture and naming the new file structure – ultimately dubbed "CCFile."

How the project was managed during execution

As NetApp became engaged with the project, they participated in weekly conference calls with DCRI. Meeting minutes and action items were documented by the vendor's PM and validated/updated by DCRI's PM before being distributed amongst all team members. This process helped both PMs to stay on the same page as it related to the project, while concurrently taking part of the documentation burden away from DCRI.

NetApp's on-site presence was primarily used for the initial installation and configuration of the NAS. Meanwhile, all of the DCRI core resources underwent a 5-day off-site training class on how to administer the system. Upon their return, multiple WebEx sessions were held with NetApp's technical engineer to put some of that knowledge into practice, particularly when it came to failing the system over between nodes and between buildings. Existing documentation from the vendor was spotty when it came to procedures, so DCRI developed their own.

One of the biggest advantages to the project was that the NAS was a completely new system, allowing a phased migration from Sapphire to CCFile. Initially, a call was made for pilot users within the DCRI to be among the first to transition their personal home directories to the NAS. Although somewhat unintentional in its duration, almost a month was dedicated to testing the migration process, failover capability, and virus scanning of the NAS using that pilot group. Among the lessons learned, the team discovered the amount of time it would take to move users based on the size of the share – a key factor in calling system downtime.

When it came time to transition users, the initial plan was to reduce the number of times users would be impacted and thereby migrate one department at a time (e.g. all of DCRI's home directories and group shares). However, within hours of the first migration, the team learned that group shares could be shared across numerous departments, ICs, and even automated system processes. Thus, a decision was made to move personal home directories first (by department), followed by group shares – both in a phased approach, 1 week apart. Unique distribution lists were created for each "group" that was moved, which reduced the amount of email clutter and potential confusion experienced by end users.

The initial schedule for all migrations was determined by the core project team based on their availability, and that schedule was shared with impacted parties, such as the User Support Team, Technical Review Board, Systems Solutions Partners, and Architecture Planning Board. Any concerns could be voiced at that time, and the schedule could be modified weeks, if not months ahead of time.

How the project was managed at Activation

The first migration took longer than expected for several reasons: An inefficient copy tool, significant numbers of temporary internet files in user's home directories, and the desire to have data copy over at 100% accuracy – a target very difficult to achieve, as many shares had hidden, locked, system, and temporary files that could not be easily migrated. To remedy this, a new copy tool was procured, temporary internet files were deleted ahead of time, and the CC CIO determined that a 99.9% copy rate would be deemed acceptable.

An activation checklist was put together for each migration, and the lessons learned from previous migrations were incorporated into each successive checklist. Thus, by the time the team had completed the migration of all personal home directories, a fairly comprehensive checklist was already in place.

To reduce the burden imposed by the 177 remaining group shares, a decision was made to retire several files and folders in place. Whenever possible, the original owner was contacted by the DCRI PM to determine the relevancy and need of those files – some of which had not been accessed in over 5 years. Ultimately, most of those shares were migrated without issue, and the others had access rights removed. The Sapphire servers were shut down at the end of the project but would remain in place for

approximately 6-12 months, just in case a retired share was still needed, or a user was unable to locate a migrated file.

The final migration – a CC share accessed by every Clinical Center employee – was completed on February 13, 2013. That migration effectively rounded out the project. A master list was created, describing the ultimate destination for all group shares. That list, along with supporting Operations and Maintenance procedures, were stored on the DCRI’s SharePoint O&M site for future reference. In response to the success of this project, the core project team (4 technical resources and the PM) received a 2012 CC Director’s Award, recognizing the work that went into “the update of the Sapphire Server involving the migration of almost 3,000 individual home directories and 170 group shares.”

Moving Forward: Additional Refinement to the DCRI Methodology

The newest process that we are looking to improve is the transition of IT systems to support once a project has been completed. Once a system is implemented we work to define the support requirements as part of project transition and this is done well on paper. The project team develops troubleshooting guides; we add the system to configuration management and review the issue notification processes with our Systems & Monitoring and our customer support teams. We still have staff who are the point of contact for 10 to 15 systems which is unmanageable. We have customers that call the original project manager for an implemented system when issues arise. Improving responsiveness to our customers and distributing the technical skills and responsibilities for ongoing technical support are goals we are working on as a department.

DCRI GUIDING PRINCIPLES

Guiding Principles are defined as a “broad philosophy” that guides an organization or department in all circumstances, irrespective of changes in its goals, strategies, type of work, or the top management. The concepts listed below are felt to embody the philosophy or principles that DCRI values as essential components in its day to day work.

Integrity

DCRI is in the business of providing a service; a service that supports the ultimate research mission at the NIH. As such, we have the privilege and responsibility of managing the very data used to make discoveries that can lead to the improved health of all people. The trust placed in our department to care for and manage this data is something that is not taken for granted. The integrity of each DCRI staff member reflects sound moral principle; uprightness, honesty, and sincerity. We adhere to the highest standards of accuracy and truth in serving our customers, users, contractors and DCRI staff.

Open Communication

Operating with a free flow of accurate and truthful information is essential to providing customer service and completing projects. Four keys to open communication that DCRI embraces are:

- Preserving the integrity of the process of communication.
- Respecting other’s point of view within the communication process.
- Being honest and accurate in all communications.
- Acting promptly to correct erroneous communications for which DCRI is responsible.

Patient and Employee Confidentiality

Clinical research requires appropriate protection of confidential and private information of both the patients, researchers and employees. With access to this information, DCRI must respect and adhere to the laws and regulations that govern our own access and use of the information. Additionally, we must ensure that access to the data contained within the various systems can be accessed only by those who have the need and the right to know. We do this via multiple physical and application security configurations that are in congruence with industry standards.

Expertise

We acquire and responsibly use specialized knowledge and experience. We value continuing education to keep our staff up to date on the latest technological advances and we routinely acquire knowledge related to the clinical systems that we manage. We believe it is essential to be respected experts in our field in order to build mutual understanding, credibility, and relationships among customers, users, contractors and DCRI staff.

IT LEADERSHIP CHALLENGES

Customer Service Improvements

Fall 2012 an independent CC group conducted focus groups with DCRI staff to develop a cross department customer service training module. As part of the focus group an evaluation of the state of the department was also determined. The main themes of the focus groups centered around what was working, what was needed and customer service training needs. Fifty-six total employees were invited across mid-level leadership and front-line employees. Seventeen focus group opportunities were conducted from October to November. Thirty four employees participated for a 62% response rate with ten of fifteen mid level leaders and twenty-four of forty employees.

A review of what was going well is provided in Table 4-2, barriers to improvement in Table 4-3 and what is needed in Table 5-4.

Table 4-2. Focus Group of What is Going Well

<p>Employees</p> <ul style="list-style-type: none"> ▫ Productivity despite problems ▫ Number of things accomplished ▫ Collegial support/sense of family ▫ Respect from and toward co-workers ▫ CRIS structure in place to meet customer needs ▫ Teamwork/willing to help ▫ Flexible work schedules 	<p>Leadership</p> <ul style="list-style-type: none"> ▫ “Service Now” ticket tracking in use ▫ Good at communicating in language that the user can understand ▫ Buffer to customer (navigating complexity without customer awareness) ▫ Monthly meetings/outreach to departments for information sharing ▫ Meeting customer needs in a timely manner
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Table 4-3. Barriers to Improvement

<p>Employees</p> <ul style="list-style-type: none"> ▫ Lack of clarity of “customer” ▫ Customer service undefined ▫ Customer expectations <ul style="list-style-type: none"> ▫ person specific versus user support ▫ Insufficient resources <ul style="list-style-type: none"> • budget, space, personnel ▫ Increased workload 	<p>Leadership</p> <ul style="list-style-type: none"> ▫ Limited resources <ul style="list-style-type: none"> • staff, space, time, geography ▫ Department culture <ul style="list-style-type: none"> • crisis mode of operation • reactive versus proactive ▫ Ineffective communication <ul style="list-style-type: none"> • top down feedback
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<p>Employees</p> <ul style="list-style-type: none"> • devices, customers, projects ▫ Technical demands <ul style="list-style-type: none"> • systems, servers ▫ Lack of infrastructure processes <ul style="list-style-type: none"> • e.g. coordination b/w problem resolution and feature requests • triage “how to” • incident vs problem management • standardization of enhancements ▫ Communication Methods ▫ Stress/Lack of Trust ▫ Silos ▫ Culture/Environment <ul style="list-style-type: none"> • emergent/crises/patient care ▫ Competing priorities <ul style="list-style-type: none"> • unclear where attention should be directed ▫ Inconsistent practices <ul style="list-style-type: none"> • ticket management, issue escalation ▫ Time <ul style="list-style-type: none"> • unrealistic deadlines, excessive meetings, 	<p>Leadership</p> <ul style="list-style-type: none"> • indirect customer feedback • insufficient follow-through (lack of commitment to respond to issues) ▫ Unclear expectations re: <ul style="list-style-type: none"> • customer service delivery • roles /responsibilities of staff (who’s who) ▫ Lack of guidelines <ul style="list-style-type: none"> • timeframes to respond/resolve • prioritization process ▫ Systems/Technical demands <ul style="list-style-type: none"> • increasing complexity • specialty areas/multiple roles • silos ▫ Increased Workload <ul style="list-style-type: none"> • devices, customers, projects, servers
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Table 4-4. What is Needed

<p>Employees</p> <ul style="list-style-type: none"> ▫ Patience ▫ Listening skills/Self awareness ▫ Technical knowledge ▫ Clear methods of communication ▫ Clear expectations ▫ Improved workflow processes ▫ Benchmarking with industry ▫ Culture shift ▫ Knowledge sharing ▫ More “service now” ▫ Leadership support/role modeling ▫ Staff buy-in ▫ Ways to value, reward staff ▫ Differentiate staff <ul style="list-style-type: none"> ▫ technical response versus customer/user response ▫ Long term planning/process improvement ▫ Ticket management analysis ▫ Trusting environment ▫ Establish policies and processes <ul style="list-style-type: none"> ▫ handling “walk ins” ▫ obtaining customer feedback 	<p>Leadership</p> <ul style="list-style-type: none"> ▫ Service Agreements <ul style="list-style-type: none"> ▫ technical and process ▫ defined timeframes ▫ accountability parameters ▫ Guidelines/Processes re: <ul style="list-style-type: none"> ▫ user expectations/customer education ▫ external and internal customer response ▫ departmental prioritization ▫ issue management ▫ section leader expectations ▫ knowledge sharing/lessons learned ▫ Standardization and consistency across teams ▫ Training to ensure technical competence ▫ Security issues clarified <ul style="list-style-type: none"> • between department and customer • procurement/maintenance ▫ Internal communication <ul style="list-style-type: none"> • point of contacts within department • defined timeframes • accountability parameters
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Based on feedback from the focus groups we are developing a plan for customer service training. A review of practices is being performed in each group and the development of key initiatives to address the findings of the focus groups.

Four key initiatives include: (1) The development of overarching guidelines and strategic goals as outlined as part of the leadership philosophy, (2) The move to the Desktop Support Service Model and the development of a knowledge base, (3) The review of how to improve communications between teams, and (4) The definition of customer service to be applied throughout the department. As part of defining customer services, we are developing a customer service training program. The curriculum of the customer service training program is below:

- Definition of customer service and customer service delivery expectations
- Communication skills and guidelines:
 - Managing up
 - Managing difficult customers
 - Managing customer expectations
 - Listening skills
 - Email and telephone etiquette
 - Self awareness/personality tests
- Assessment of Technical knowledge requirements

Resource Challenges/Project Requirements

Information Technology Advisory Board (ITAG) has been beneficial in reviewing and prioritizing projects. However, there is a large number of projects on our plates. To be efficient based on the size of the organization, the Portfolio Management Group has identified that we can participate in 20 projects at one time. Our current project load is at 32 projects being conducted. Based on sharing the same technical resources for O&M and projects it is difficult to maintain the current work load without balancing the affects it has on the progress of both.

To manage the project load, we have identified the amount of hours assigned by team for projects, and our team leads work to maintain these values. The hours required to start a new project is considered by ITAG when making recommendations to approve new projects.

The tables below demonstrate an analysis recently performed to quantify technical resources available to implement multiple IT projects which are part of the CC Insurance Billing Pilot (IBP) pilot and impacts on current projects. Figure 4-1 and Table 4-5 show the current hours worked by staff in relation to scheduled hours. Figure 4-2 reviews the hours by quarter and the projected hours required based on the scheduled projects. The cells in pink show teams for which the hours forecasted are greater than the amount of hours available. The table labeled IBP shows the additional staff that will be available as part of the IBP project.

Figure 4-1. Actual Hours Worked Versus Scheduled Hours by Team

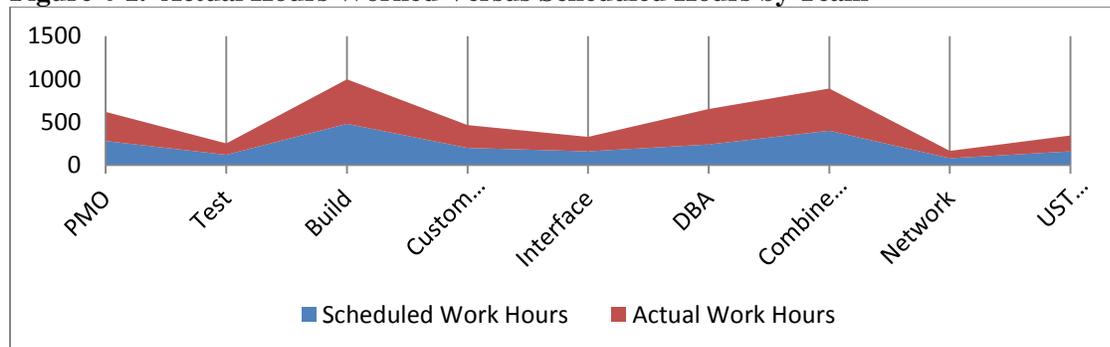


Table 4-5. Actual Versus Scheduled Hours

	PMO	Test	Build	Custom Apps	Interface	DBA	Combined Sys Admin	Network	UST Projects
Number of Employees	7	3	12	5	4	6	10	2	4
Scheduled Work Hours	280	120	480	200	160	240	400	80	160
Actual Work Hours	338	132	517	265	168	412	490	85	184
Total FTES	8.5	3.3	12.9	6.6	4.2	10.3	12.3	2.1	4.6

Figure 4-1. Forecasted Project Hours by DCRI Technical

TOTALS - All non-TPR

Team	Avail	Jul13	Avail	Aug13	Sep13	Avail	Oct13	Nov13	Dec13
PMO	768	799	768	675	577	768	477	427	317
Test	264	275	264	239	235	264	160	148	107
Build	360	240	360	270	285	360	251	235	232
Appl. Dev	360	420	360	345	340	360	188	184	34
Interface	198	164	198	174	138	198	101	69	41
DBA	216	227	216	204	150	216	130	131	121
SA-Citrix	96	99	96	102	84	96	90	81	81
SA-Non-Citrix	120	137	120	112	25	120	14	14	9
Network	64	77	64	52	48	64	4	9	4
UST Projects	480	440	480	400	270	480	300	250	62

TOTALS - TPR

Team	Avail	Jul13	Additional	Aug13	Sep13	Additional	Oct13	Nov13	Dec13
PMO	768	160		195	205		220	260	285
Test	264	25		65	125		120	165	95
Build	360	165	200	195	270	420	250	285	305
Appl. Dev	360	45		60	60		115	125	145
Interface	198	35		70	145		190	200	155
DBA	216	25		20	25		20	30	20
SA-Citrix	96	0		0	0		0	0	0
SA-Non-Citrix	120	5		5	5		5	5	5
Network	64	0		0	0		0	0	0
UST Projects	480	30		30	50		130	125	110

TOTALS - All

Team	Avail	Jul13	Avail	Aug13	Sep13	Avail	Oct13	Nov13	Dec13
PMO	768	959	768	870	782	768	697	687	602
Test	264	300	264	304	360	264	280	313	202
Build	360	405	560	465	555	780	501	520	537
Appl. Dev	360	465	360	405	400	360	303	309	179
Interface	198	199	198	244	283	198	291	269	196
DBA	216	252	216	224	175	216	150	161	141
SA-Citrix	96	99	96	102	84	96	90	81	81
SA-Non-Citrix	120	142	120	117	31	120	19	19	14
Network	64	77	64	52	48	64	4	9	4
UST Projects	480	470	480	430	320	480	430	375	172

Organizational Expectations

IT infrastructure including application development, desktop support, cell-phone and smart phone coverage, system implementation and system support are similar to electricity and should always be available for organizations to run effectively. Our customers share their expectations that there should be no performance issues and no downs. Cell phones, smart phones, laptops and desktops should perform at work like they do at home. The challenge for DCRI is that the business environment is complex, in some cases relies on services that are provided by others and requires maintenance on regular basis for optimal performance. As we increase the number of systems, the variety of devices for users and projects, the amount of resource hours for O&M increases too. As a result of incorporating more technology in our business processes, DCRI's ability to perform O&M activities must be factored into the amount of projects and systems that are implemented.

Maintaining Service across Inpatient Units and Outpatient Areas: Clinical Reliable Equipment Assessment and Corrective Action

Objective: The existing infrastructure in regards to the performance and support of the Workstation on Wheels (WOWs) and the Wireless to support the WOWs was not meeting the requirements of the organization. To provide a clinical reliable environment the milestones and timeline below was identified.

Event	Team	Date
Wireless N CC Wide	CIT/DCRI	Complete
Evaluation of Carts for 2014/ 75 a year	Nursing/Pharmacy – DCRI	Complete
Monitor Wireless Devices From User Experience	CIT/DCRI	October 2013
Green Tag Device Replacement Process	DCRI/Nursing	March 15, 2013
Upgrade WOW Computer/Upgrade WIN7 32 Bit	DCRI	September 15, 2013
Upgrade WOW OS/Upgrade to WIN7 64 Bit	DCRI	Fall 2013
Inventory of Devices	DCRI	August 12, 2013
Deploy New Printers in Select Areas	DCRI	Early Fall 2013
Wireless Scanners	Nursing/Pharmacy – DCRI	Ordered 8/20/2013
Inventory of Devices	DCRI	August 12, 2013
Assess Additional Devices/Discuss Deployment	Med Admin PM Team	Today
Deploy For Pilot (WOWs to Arrive W/ Devices)	DCRI (Arrive 10/11/13)	Mid Fall 2013
Improve Support to Devices Business Hours	DCRI	Early Fall 2013
Improve Inventory Management	DCRI/Nursing	Early Fall 2013
Update Scanners To Reflect No Need for Asterisk	DCRI	Late Fall 2013
Improve Support to Devices/Off Business Hours	DCRI	Winter 2013

Maintaining Service across Departments: Desktop Support

Objective: As part of desktop support, DCRI provides support to over 8000 computer devices including laptops, desktops, printers and mobile devices as well as over 4000 users of multiple clinical and administrative systems. Currently we have 15 user support staff members providing Tier 2 support with no service center or service center or Tier 1 support. The 15 staff members are assigned as a primary and secondary support for over 20 offices and departments. Based on the number of staff one person could be the primary for multiple departments.

Problems with the current model of people assigned to offices and departments with no Tier 1 support include not all tickets tracked, low customer satisfaction, low staff satisfaction (burn out, frustration), no formal request process resulting is departments and offices grabbing staff to have computer issues resolved, limited standardization across Tier 2 support and departments, limited cross training, and no true metrics based on not having Tier 1.

The new business process starts and depends with the user contacting the call center. Without a call to the call center then we will not be able to improve first call resolution which is the basis to improve efficiency and customer satisfaction. The call center will work with the customer to resolve 50-60% of the issues. Only those tickets in which the call center are unable to resolve in a timely manner are delegated to Tier 2. By requiring all tickets to start with a call to the call center the ability to document and manage all tickets and all support will now be possible. As a result the new proposed team allows a division of labor across multiple groups to ensure a more efficient process resulting in a higher customer satisfaction. The groups include the call center focused on resolving a set of tasks, the Tier 2 set to resolve issues that require deployment and increased time allotment for resolution, a leadership team to manage the workflow between the call center and Tier 2 that will work to improve the knowledge and ability to resolve tasks of the call center and Tier 2.

The rollout of the Desktop Support Service Model is as follows

- Phase 1: July 29, 2013: Social Work Department, Safety Office, Nursing - Mgmt & Admin, Patient PC, Duke Room, NIH School, Nuclear Medicine, PET
- Phase 2: August 19, 2013: RMD, Nutrition, MRD, OPS, Biostatistics, HES, CRTP
- Phase 3: September 30, 2013: Inpatient/Outpatient Areas Admissions, ACS, Dental, DTM, MMD and Housekeeping
- Phase 4: November 11, 2013: DLM and Phlebotomy
- Phase 5: January 6, 2014: Pharmacy, Animal Protocol
- Phase 6: February 17, 2014: DRD, LDRR
- Phase 7: March 31, 2014: CCMD, ICU, OD

Maintaining Service across Departments: Service Level Agreements

A service-level agreement (SLA) is a negotiated agreement between two parties where one is the customer and the other is the service provider. The SLA records a common understanding about services, priorities, responsibilities, guarantees and warranties. Each area of service scope should have the 'level of service' defined. The SLA may specify the levels of availability, serviceability, performance, operation, or other attributes of the service such as billing.

DCRI has a base level SLA with each CC Department for Technical Desktop Support and for CC Departments which utilize the Data Center for Department Operated Systems which include the Department of Radiology and Imaging Sciences, Department of Transfusion Medicine and the Laboratory of Informatics Development. Below is an example of the SLA with the Laboratory for Informatics Development for the NIH Biomedical Translational Research Information System (BTRIS) project.

Table 4-6. SLA Table of Contents

Introduction
Hardware Specifications
Facilities
Physical Facility
Network
Service Level Agreement
CC Data Center Responsibilities
• Storage Area Network (SAN):
• Firewalls and Host-Based Security
• Monitoring
• Audits
• Disaster Recovery Service
• Incident Communication/Escalation
Customer Responsibilities
• Monitoring
• Labor
• Incident Communication/Escalation

We are developing a more complete Departmental SLA to review the specific IT needs and expectations for each Department. Services covered within the SLA include:

- IT Data Storage
- IT User Support
- IT Conference Rooms
- IT Equipment Procurement
- IT Office Equipment Spares
- IT Infrastructure and Network
- IT Security and Monitoring
- IT Application/System Support
- IT Web Hosting
- IT Remote Access
- IT Desktop
- IT Application Hosting
- CC Data Center Hosting
- Clinical Data Repository
- CRIS/SCM Interfaces and Data
- CRIS/SCM Configuration and Build
- CRIS/SCM User Support and Training
- Point of Care Devices Support

Below is an example of the SLA being developed with the Department of Radiology and Imaging Sciences with the complete SLA shown in Appendix D. We will be working to develop SLAs with each CC Department and all ICs that have systems that interface with CRIS.

Figure4-2. Excerpt of RADIS SLA

Goals:

The goal of DCRI is to provide modern, timely, state-of-the-art hospital IT services to the RAD&IS department. The goals of RAD&IS Department are to provide advanced clinical procedures and research to CC. The goals of this document are to codify the IT policies and procedures necessary for the CC, DCRI and RAD&IS to meet their joint NIH mission.

Expectations:

DCRI recognizes its customers demand modern, timely, state-of-the-art IT services. DCRI also recognizes there are many supply sources for these IT Services and it must continually earn the right to supply them. As such DCRI strives to provide the best service in a timely manner, integrate new technologies into the Enterprise, increase the utility and availability of services, and support the RAD&IS's clinical operations and research. DCRI understands that success depends not only a timely and reliable deliverable of service but an open communicative and collaborative process between DCRI and RAD&IS.

DCRI expects to deliver the following services:

IT User Support:

Tier Level	Provider	Access Method	DCRI Technicians Assigned
1	DCRI Service Center	Phone, Web	Multiple Staff
2	DCRI	NIH IT Service Desk	2
3	System Expert	DCRI	NA

IT User Support for CRITICAL Issues Resolution:

Metric Description	DCRI Time	Elapsed Time	Method
Tier 1 DCRI Service Center call answered	< 1 minute	<1 minute	Phone call
Tier 1 DCRI Service Center support ticket created, trouble shooting and Tier 2 technician assigned	< 15 minutes	< 15 minutes	Email is sent automatically
Tier 2 Technician initial response time	< 30 minutes	< 45 minutes	Phone or email to acknowledge ticket
Tier 2 Technician on-site	< 25 minutes	< 1 hour	In-person visit
Tier 2 Technician resolution	< 60 minutes	< 2 hours	Solution installed or spare replacement initiated
Tier 3 Escalation decision	< 2 hours	< 4 hours	Tier 2 Technician notifies DCRI System Expert

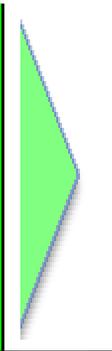
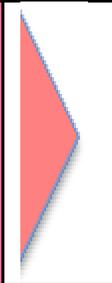
Maintaining Service across Systems: System Monitoring Program (SMP)

Objective: As part of the 36 Hour down of CRIS in 2010 we recognized that our monitoring tools in respect to CRIS and the CC IT Infrastructure needed improvement. To focus on Monitoring, the first step was to create a monitoring program. To accomplish this objective the following tasks are within scope:

1. Define and approve the documentation needed to implement and support a monitoring program, to include:
 - a. Program Charter
 - b. Program organizational structure, membership, roles and responsibilities
 - c. Program reporting structure related to other DCRI teams and committees
 - d. Training plan
 - e. Program workflows, process flows and data flows
 - f. Process for monitoring current systems and adding/updating systems to the program
 - g. Process for evaluating and resolving unscheduled downs and performance impacts.
 - h. Associated SOPs for the program
2. Ensure all DCRI staff is aware of monitoring program and training is completed according to training plan.

Roadmaps:

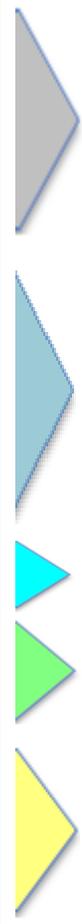
The increase of project work and increase in operations and maintenance has resulted in the need to become more strategic with all aspects of work. To plan across the department, the concept of Roadmaps for each area is being developed. The initial development of roadmaps is reviewed on the following pages.

<p>PMO: Cornerstone Projects</p>	<ul style="list-style-type: none"> • Patient Portal Phase 1 • Patient Portal SHM • KBMA Pilot • System Monitoring Program (SMP) • Architecture Simplification (AS) • Clinical Reliable Equipment Assessment and Corrective Action 	<ul style="list-style-type: none"> • KBMA Roll Out • Enterprise Scheduling • CRIS SCM 6.X 	<ul style="list-style-type: none"> • Referring Portal • Order Reconciliation • Document Management 		
<p>Insurance Project</p>	<ul style="list-style-type: none"> • NPI • Insurance Collection • IMO/Diagnosis • Staging Database • Billing Interfaces • Billing System • Billing/Non-Billing Segregation 	<ul style="list-style-type: none"> • Procedure Orders • ProVation Interfaces • ICD 10 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • 	
<p><i>Years</i></p>	<p><i>2013</i></p>	<p><i>2014</i></p>	<p><i>2015</i></p>	<p><i>2016</i></p>	

PMO Maturity: Software	<ul style="list-style-type: none"> Procure APM/PPM Tool 	<ul style="list-style-type: none"> Consolidate PM Tools (SP, SBM, PPM) 	<ul style="list-style-type: none"> Automated Reporting & Dashboards 	
PMO Maturity: Process	<ul style="list-style-type: none"> Educate DCRI Leads 	<ul style="list-style-type: none"> Program Management Streamline Project Charters 	<ul style="list-style-type: none"> Standardize Analyst Role FAC-PPM Competency 	<ul style="list-style-type: none"> Review/Revise Explore Agile Processes
Testing: Software	<ul style="list-style-type: none"> Procure/Install Quick Test Pro 	<ul style="list-style-type: none"> Regression Testing Development o WebApps 	<ul style="list-style-type: none"> Regression Testing Development o Custom Apps 	
Testing: Processes	<ul style="list-style-type: none"> Update Process & Templates 	<ul style="list-style-type: none"> Educate & Communication 	<ul style="list-style-type: none"> Review & Revision 	
<i>Years</i>	<i>2013</i>	<i>2014</i>	<i>2015</i>	<i>2016</i>

EA: Technology Retirements	<ul style="list-style-type: none"> 802.11G 2G 	<ul style="list-style-type: none"> Lotus Notes PowerBuilder Sunray MS Office 2007 & 2008 XP Vista MAC Snow Leopard 	<ul style="list-style-type: none"> Sybase Sybase Mobile (cBord) FoxPro 	<ul style="list-style-type: none"> Ruby on Rails 4D
EA: New Technologies	<ul style="list-style-type: none"> 802.11N NAS CITRIX XEN 6.5 	<ul style="list-style-type: none"> DMZ IDS Explore Disaster Recovery at Sterling 	<ul style="list-style-type: none"> Explore Areas for Cloud Upgrade Virtualization 	<ul style="list-style-type: none"> 802.11x
EA Maturity: Process	<ul style="list-style-type: none"> Integrate o CMO/PM/Request Process/EA/S&A 	<ul style="list-style-type: none"> Future Tech Review Continued Education 	<ul style="list-style-type: none"> Review and Revise 	
Security: O&M	<ul style="list-style-type: none"> Nessus Scans Web AppScans S&As Incident Response Annual PIA Annual Training 			
Security: HIPAA	<ul style="list-style-type: none"> Policy Development Risk Assessments 			
<i>Years</i>	<i>2013</i>	<i>2014</i>	<i>2015</i>	<i>2016</i>

CRIS: Orders	<ul style="list-style-type: none"> • Develop Protocol Order Set Request Process • Develop New Chemo Order Set Template • Develop RADIS Quick Orders • Revise RADIS Orders • Revise Serial Test Orders • Continue to Update Pharmacy Orders • Pharmacy IV Orders to Flowsheets 	<ul style="list-style-type: none"> • Revise Laboratory Orders • Revise all System Orders • Continue to Update Pharmacy Orders 		
CRIS: Clinical Documentation	<ul style="list-style-type: none"> • QuickNotes • Replace eSphere Pain & Palliative System • Transplant Documentation • Acuity Plus/Transparent Documentation 	<ul style="list-style-type: none"> • Mandate of Electronic Progress Notes Outpatient • IMO/Diagnosis/Health Issues • Discharge Summary Improvement 		
CRIS: DBA	<ul style="list-style-type: none"> • DB Monitoring • Corman Monitoring 	<ul style="list-style-type: none"> • Migrate to MS SQL 2012 	<ul style="list-style-type: none"> • Migrate to Virtualization 	
CRIS: New Modules	<ul style="list-style-type: none"> • Patient Portal Phase 1 • Patient Portal SHM • KBMA Pilot 	<ul style="list-style-type: none"> • KBMA Roll Out • Enterprise Scheduling • CRIS SCM 6.X 	<ul style="list-style-type: none"> • MD Portal • Order Reconciliation 	
Clinical Systems: O&M Upgrades	<ul style="list-style-type: none"> • Omnicell • CITRIX 	<ul style="list-style-type: none"> • Theradoc • CBORD • SCM 6.X • Virtualization • RIS 	<ul style="list-style-type: none"> • DMZ • LIS • Patient Portal • Referring Portal • ScriptPro Outpatient Pharmacy 	<ul style="list-style-type: none"> • SCM 7.X • SIS
<i>Years</i>	<i>2013</i>	<i>2014</i>	<i>2015</i>	<i>2016</i>



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SECTION 4

STAFFING

Staff Utilization

An article from the American Medical Informatics Association 2008 Symposium Proceedings (Hersh, Wright) states that for a Level 4 system the number of hospital IT staff should be equal to 21% of its total number of beds. The Clinical Center has 240 beds, which translates into a need for approximately 50 IT staff. DCRI has 52.25 IT staff supporting CRIS—55.15 FTE and Contractors. As explained within the Budget section, given the NIH's focus on research, DCRI includes a Clinical Informatics Section which in many facilities is under Nursing. While these additional staff is assigned to DCRI, others are not. For example, DCRI does not support financial systems, and several clinical departments (e.g., Radiology and Imaging Sciences Department and Department of Transfusion Medicine) support applications separate from those owned and administered by DCRI; therefore additional staff to support these activities are not included in DCRI's staffing numbers.

Staffing Model Analysis

During 2006, 2011 and 2013 an analysis was performed on the staffing usage within DCRI to understand the staff configuration and to identify the staff usage by functional category. As of August 2013, DCRI was comprised of 98.4 full-time government employees and 9 full-time contractors.

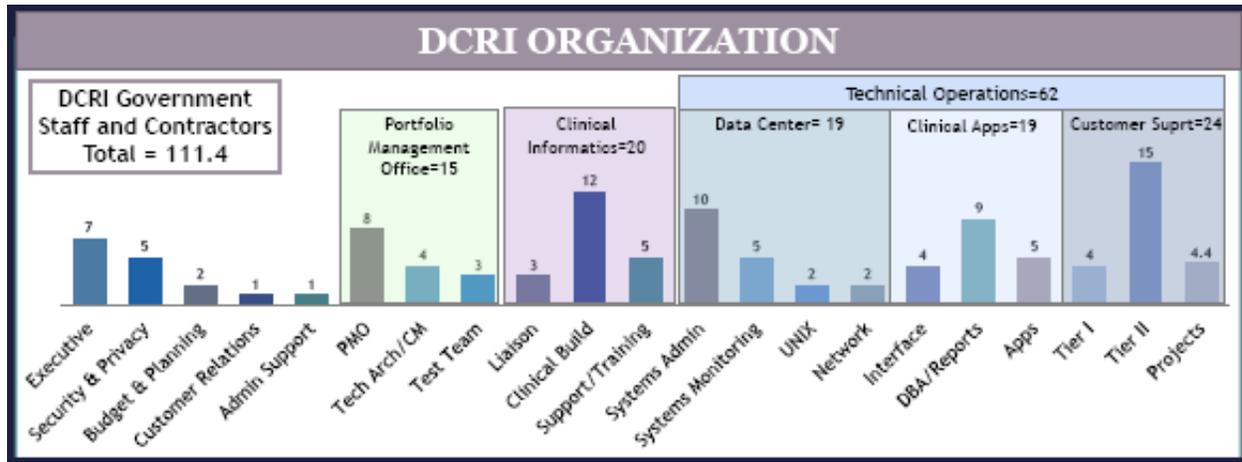
The goals of the analysis included:

- Examining time allotment for projects.
- Understanding how IT department can supports existing technology while developing new technology.
- Defining activities that are classified as Operations and Maintenance.
- Quantifying Operations and Maintenance.

Methodology

- Updated DCRI Team Organization Chart
- Categorized daily activities into Business O&M, Systems O&M, and Projects
- Met with staff members to collect average number of hours spent on daily activities (based on a typical work week)
- Analyzed new data.
- Compared and contrasted 2013 data with previous years of 2006 and 2011.

Figure 4-1. Staffing Analysis



Results

Figure 4-2 reviews the outcome of the staffing model analysis. The analysis showed that System Operations and Maintenance (Configuration Management, System Maintenance, Call Center Tickets, Security, Routine Functions, and CERC) make up 53% of the activities, Business Operations and Maintenance (Administrative meetings, business process analysis, procurement) 24%, and Projects 23%. With only twenty three percent of the time available for projects, the ability to meet the demand for new technologies and new projects is a challenge as Operations and Maintenance continues to increase. The benchmark according to Gartner is 35% devoted to Projects and the remaining two Operations and Maintenance (O&M).

Conclusions of the Study

- Roughly 65% of the department government staff more than the “typical” 40 hour week.
- The 65% of staff work approximately 12.7 hours of overtime per week.
- DCRI has shifted from Systems O&M to project work from 2006 to 2013 from 13.6% to 23%.
- The total number of systems DCRI manages has increased by 61 clinical and administrative systems from 2008 to 2013 while systems operations and maintenance dropped from 66 to 53% during this same time.
- The number of desktop devices (SunRays, Laptops, Desktops, Workstation on wheels, barcode PDA devices and printers) has increased from 5672 to 7270 from 2008 to 2013 for a 28% increase.
- The number of servers has increase from 439 to 760 for an increase of 321 from 2008 to 2013 for an increase of 73%.
- The amount of time devoted to O&M has not increased based in relation to the number of systems supported.
- The increase of time devoted to projects has resulted in the time dedicated to Systems O&M decreasing.

Figure 4-2. Staffing Analysis Results

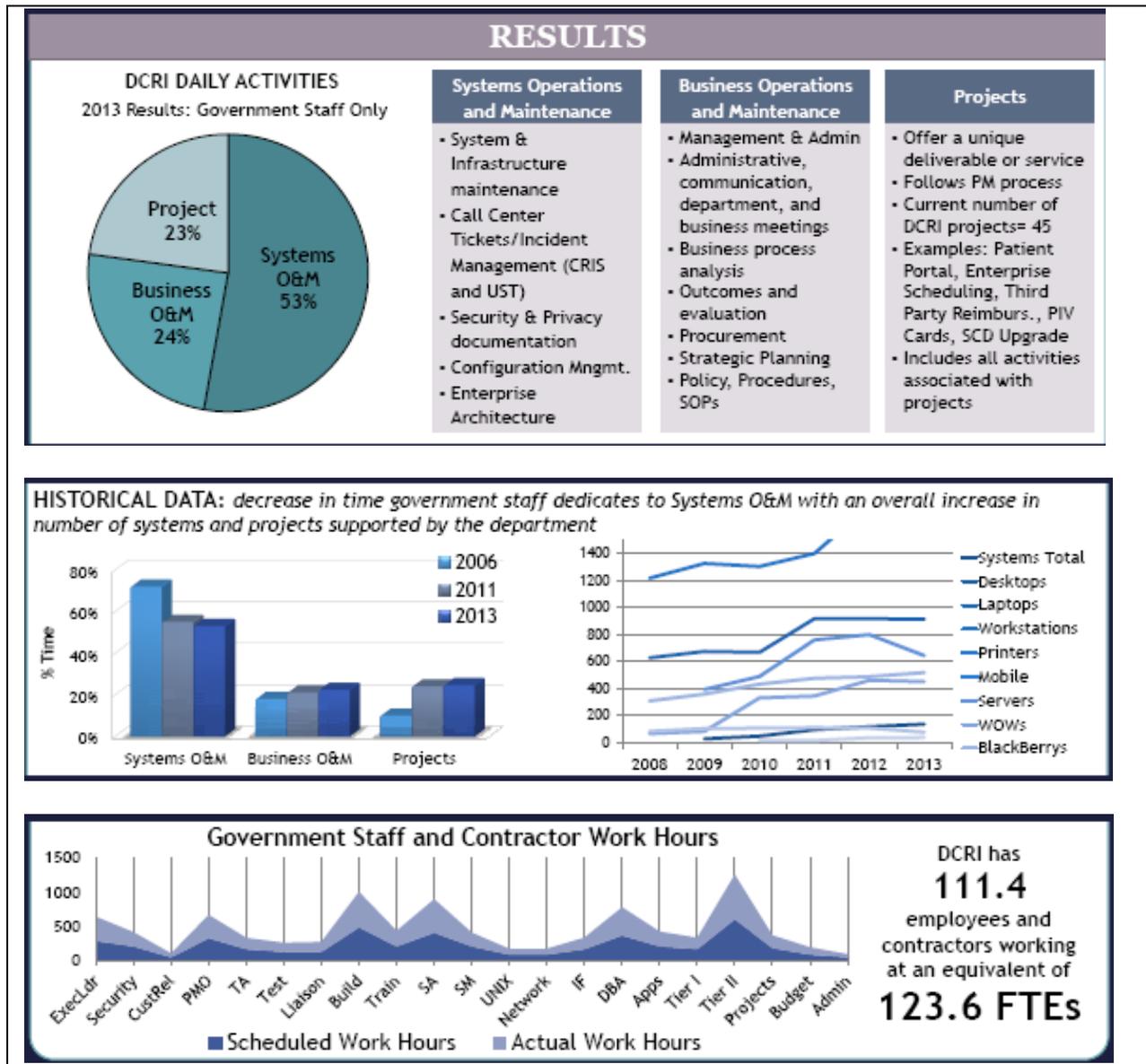


Table 4-1. Desktop Support Metric 1999 – 7/2013 Model

Industry Targets			
Description	Computers	Industry Target	Current Staff
Tier II Support: installations, moves, adds and changes (IMAC). 1 Tech per 300 – 350 Computers (based on having a Tier I Support).	5736	16 – 19 Tier II with (4-5 as part of Tier 1)	15, with no Tier 1
Clinical Call Center		2-3	1-2

The ratios above are based on information gathered from client inquiries and Gartner Reports. They represent ranges sufficiently wide that approximately 80% of organizations should find themselves somewhere in a particular range. There are certainly organizations that are advanced or in an industry that constrains IT spending that would place them outside these ranges. Gartner Summit Events, Ed Holub, May 2008.

Table 4-2. Server Administrator Support Metric

Metric	Gartner Target	Number of CC Servers	Required Staff Per Gartner	Number of DCRI Staff
UNIX Administrator	1 administrator per 10-50 servers	23 Unix Servers	1 – 1.5	1.5 dedicated to O&M
Windows Administrator	1 administrator per 16-75 servers	341 Windows Servers (non-SCM)	3.06 – 15.33	4 staff members dedicated to O&M
CRIS Windows Administrator	1 administrator per 16-75 servers	75 Windows Servers (dedicated to SCM)	2	2 Dedicated to O&M

The Windows server range is very wide in order to accommodate more resource-intensive servers, such as database servers, as well as less resource-intensive servers often configured into "farms," such as Web and application servers. Clients report Unix server ratios are typically somewhat lower than Windows. The server ratios are based on operating system instances rather than physical servers. Gartner Summit Events, Ed Holub, May 2008.

Staff Resumes of DCRI Leaders

Jon Walter McKeeby, D.Sc.
Chief Information Officer



ACADEMIC DEGREES/CERTIFICATIONS

Doctorate of Science in Computer Science (2001)

George Washington University, Washington, DC

Major: Software and Systems; **Minors:** Multimedia, Human Factors

Dissertation title: “Examining the Role Media Attributes Play in Multimedia Applications”

Master of Science in Computer Science (1990) Bowling Green State University, Bowling Green, OH

Bachelor of Science in Computer Science (1988) Hope College, Holland, MI

RELEVANT EXPERIENCE

Clinical Center, National Institutes of Health (May 1991 to Present)

CIO, NIH Clinical Center (August 2006 to Present)

- Manage the Department of Clinical Research Informatics which includes the three areas of Technical Operations, Clinical Operations and Clinical Training and Evaluation. Interact with NIH CC Clinical Departments and NIH Institutes for IT issues and services for the Clinical Research Information System, Ancillary Systems and IT Support.

Interim CIO, NIH Clinical Center (January 2006 to August 2006)

Deputy CIO, Technical Operations, Department of Clinical Research Informatics (January 2005 to January 2006)

- One of three Deputy CIOs reporting to the NIH Clinical Center CIO. The Technical Operations position has responsibility for the following IT areas: PC User Support, NT Server Administration, Clinical Database Repository, Clinical Systems Administration, Systems Monitoring, and Property & Asset Management.

Architect, Department of Clinical Research Informatics (December 2002–2006)

- Architect for the Clinical Research Informatics System (CRIS) Project. Key systems are listed below:
 - **Allscripts Sunrise Clinical Manager: (September 2002 – August 2004)**
The Project included planning, selection, and installation of the Allscripts Sunrise Clinical Manager. The modules installed included: orders, results, clinical documentation, CPOE, and medical administration of medications using the clinical work-list. This role was focused on participating in decisions related to definition of key clinical application system parameters, interface planning and development; data migration from the legacy system into the procured system; and testing/configuration management.
 - **SIS (Surgical Information System): (September 2004 – 2008)**
Technical and clinical lead involved from initial vendor selection through system installation. Project is currently in the installation phase.
 - **ADT/Pre-registration System: (September 2004 – 2008)**
Consultant for process design, SCM design, interface development, training, testing and go-live activities.
 - **Scheduling System: (September 2004 – December 2005)**

- Consultant for process design, interface development, training, testing and go-live activities.
- **CBORD Dietary System: (September 2002 – April 2004)**
Consultant for process design, interface development, training, testing and go-live activities.

Computer Specialist, NIH Clinical Center, Information Systems Department (September 1995 – December 2002)

Positions held within the Information Systems Department are listed below:

- **Development Team Leader (September 1995 – December 2002)**
Managed a staff of ten employees (including database designer, Sybase DBA, interface programmer, interface administrator, tester, and Unix administrator). Key projects included:
 - **Radiology System:** Managed interface development between the Allscripts Sunrise Clinical Manager, the Cerner Corporation System, and the NIH CC Clinical Database Repository.
 - **Lab Information System:** Managed interface development between the Allscripts Sunrise Clinical Manager, the Soft Computer Corporation System, and the NIH CC Clinical Database Repository. The Soft Computer Corporation System includes the Lab, Blood Bank, Microbiology, and Anatomic Pathology Modules.
 - **SoftMed Transcription System:** Managed interface development of between the Allscripts Sunrise Clinical Manager and the SoftMed Transcription System.
 - **Hospital Statistics System:** Designed, developed, and maintained the hospital statistics system. This event-tracking system reports hospital measures (radiology, pharmacy, inpatient days, outpatient visits, nuclear medicine, clinical pathology, and positive emission tomography [PET] events).
- **Web Team Leader (October 1998 – December 2000)**
Managed the web development for NIH CC by five employees including 1 project manager, 3 HTML programmers, and 1 ASP programmer).

Computer Specialist, Medical Record Department (May 1991 – September 1995)

- Designed, developed, and maintained multiple microcomputer databases within 4th Dimension, supported 30 computer users, and developed user documentation.

PUBLICATIONS

- Way, Cynthia & Jon W. McKeeby. 2012. Systems Thinking as a Team-Building Approach Reflections: The SoL Journal, Volume 11, Number 4, February 2012, pp. 44-49(6). Publisher: Society for Organizational Learning.
- Cimino, JJ, Farnum, L, Cochran, K, Moore, S, Sengstack, P & J. McKeeby. (2010). Interpreting Nurses: Responses to Clinical Documentation Alerts. Proc 2010 AMIA Fall Symposium, Washington, DC, 2010.
- Haerian K, McKeeby J, DiPatrizio G & JJ Cimino. (2009). Use of Clinical Alerting to Improve the Collection of Clinical Research Data. Proc 2009 AMIA Fall Symposium, San Francisco, CA, 2009: 218-222.
- McKeeby, Jon W. & Karlyn A. Barilovits. (2008). Synchronous Course Component Increases Student Success. Kaplan University Online Conference.

COMPUTER SKILLS

Databases and Database Tools: Sybase©, ORACLE©, MS SQL Server©, Transact SQL, Erwin©, ACIUS 4th Dimension©

Interface Engines: Quovadx© CloverLeaf Engine Management, HL7 Standards

ADDITIONAL EXPERIENCE

Kaplan University (Fall 2005 - Present)

Adjunct Professor Kaplan University (Fall 2005 - Present)

Bachelor of Science in Information Technology Program:

- IT163: Intro to Database Management, IT350: SQL Design, IT354: Database Design, IT452: Database Administration in MS SQL 2005, IT428: Application Development for Healthcare, IT456: Advanced SQL, IT457: Data Warehousing and Data Mining

Master of Science in Information Technology Program (Fall 2008 - Present)

- IT520: Database Design, IT522: Knowledge Management, IT523: Data Warehousing and Data Mining

Course Lead/Developer

- IT456: Advanced SQL, IT520/IT525: Database Design, IT522: Knowledge Management, IT523: Data Warehousing and Data Mining

Master of Science in Information Technology Program: Graduate School of Management and Technology, University of Maryland University College (Fall 2001 - Spring 2004; Spring 2010 - present). Adjunct Professor.

- **DBST 651: Relational Database Systems: Face To Face** (Spring/Summer/Fall 2002/2003/2004) **Distance Education** (Fall 2002, Spring/Fall 2003, Spring 2004, Fall 2012). Course covers relational database design, normalization, data modeling, and Oracle SQL.
- **DBST 665: Data Warehouse Technologies Distance Education** (Summer/Fall 2010, Fall/Spring/Summer 2011/2012/2013). Course covers data warehouse design and development.

AWARDS

NIH Director's Award. (June 2013) Team award for CC Data Transformation Initiative Project.

NIH Clinical Center Director's Award: Strategic Award. (December 2012) Award for outstanding leadership of IT initiatives focused on the improvement of clinical care, patient safety and operational efficiencies.

NIH Clinical Center Director's Award: Strategic Award. (December 2012) Team award for implementing a pharmacogenomics testing program to improve the safety of drug therapy.

NIH Clinical Center Director's Award: Strategic Award. (December 2008) Award for coordination of multiple strategic initiatives with impact reaching throughout the Clinical Center.

NIH Clinical Center Director's Team Award: CRIS Installation Team. (December 2004) Team award for the successful completion of the replacement of all NIH Clinical Center clinical systems (order management, clinical documentation, CPOE, and interfaces).

NIH Clinical Center Director's Team Award. Strategic Initiatives: PACSweb Implementation Team. (November 2002). Team award for furthering Clinical Center strategic goals by implementing PACSweb, improving patient care and research, and serving as exemplars of intradepartmental cooperation.

NIH Director's Team Award. (June 1996). Presented in recognition of administrative support in the development and expansion of intramural research protocol data management services.

NIH Clinical Center Director's Award. (April 1996). Presented in recognition of the development, maintenance, and revision of SACRED, an Automated Credentialing System.

JAMES T. PITTS
Chief of Technical Operations



ACADEMIC DEGREES/CERTIFICATIONS

Prince George's Community College – Largo, Maryland
1989 to June 1991

Completed 54 credit hours towards A.A in Engineering

Prince George's Community College,
Associate of Arts Degree – General Studies, June 1986

RELEVANT EXPERIENCE

Clinical Center, National Institutes of Health (January 1997 - Present)

Chief of Technical Operations, Department of Clinical Research Informatics (November 2010 - Present)

- Manage the Technical Operations Section of DCRI, which is comprised of the following teams: Systems Administration, Unix Administration, Systems Monitoring, Network, Clinical Database, Interfaces, Administrative Database, Custom Applications and Customer Support.
- Manage Human Resource matters for the Department. Develop Position Descriptions, hiring documents and mentor staff in managing personnel issues.
- Serve as Contract Officer Technical Representative (COTR) on various contracts.
- Implemented and manage the Clinical Center mobile device management system.
- Sever as project manager on various projects.

Chief of Policy, Planning, Applications and Databases, Department of Clinical Research Informatics (November 1999 – November 2010)

- Managed the Custom Applications, Database and Unix Teams.
- Managed Human Resource matters for the Department which included mentor to the Department Team leaders and Supervisors and help with all personnel issues including promotions, hiring new staff and performance problems.
- Worked closely with the Administrative Officer and Human Resources to develop position descriptions and evaluation criteria for all new department vacancies.
- Served as Contract Officer Technical Representative (COTR) on various contracts and manage the contract staff. Serve as Project Manager on various projects.

Computer Specialist, Information Systems Department (January 1997 -November 1999)

- Supervised staff on a day-to-day basis, ensuring adherence to established policies, procedures, work methods, and standard practices. Provided overall direction and supervision of the development and maintenance of all ancillary Clinical Center systems.
- Provided overall direction and supervision of the UNIX systems and firewall.
- Provided budget development, procurement, and tracking for the Section.
- Provided contract documents including Requirements Analysis, Acquisition Planning, Statement of Work, Government Cost Analysis, and Source Selection.
- Provided project management for the development of administrative applications.
- Maintained the Clinical Center hospital statistics database and provide over 200 monthly and quarterly reports.
- Managed a project to provide flat panel computer workstations in the hospital wards. This included: reviewing flat panel display technology, designing the cabinet to house the computer and flat panel displays, initiating and managing the contract to build and install the product.

- Managed the development of the CCLink application which graphically links data elements to floor plans of NIH campus buildings and is used to map LAN and telephone systems. This application was moved to the NIH/Center for Information Technology (CIT) as a campus-wide system.

Engineering Technician, Division of Engineering Services (DES), DCB, Team 2 (May 1989 - January 1997)

- Provided architectural design and contract services.
- Introduced Computer Aided Design (CAD) to the Design and Construction Branch with the procurement of three CAD stations and demonstrated a major increase in productivity.
- Expanded the CAD system by designing, procuring, and installing a UNIX network, twenty-five workstations, two file servers, two database servers, optical disk storage, and three plotters.
- Developed custom user interfaces to the campus floor plans and data. Provided customer support and end-user training. Planned and developed Internet access to facility information and image data using HTML and WEB Page technologies.
- Provided system migration and integration from a proprietary Intergraph system running under UNIX to an open systems architecture using Microsoft NT, Oracle, and PowerBuilder technologies.
- Developed Acquisition Planning Requests for new contract initiatives including: historical data, acquisition planning, cost and benefit analysis, and requirements analysis.
- Contract Technical Representative for a \$2.5 and a \$10 million ADP contract. Wrote Tasks Orders, reviewed and approved cost submittals and delivery schedules.

ADDITIONAL EXPERIENCE

Bowie Volunteer Fire Department - *Served sixteen years as a Volunteer Fireman reaching the rank of Assistant Chief, managing Bowie Station 39. Served as an Emergency Medical Technician.*

AWARDS

NIH Director's Award – CC Data Transformation Initiative Project - June 2013

Clinical Center Director's Award – 1999, 2004

Recognition and Appreciation of Special Achievement July 27, 1998, Michele Lagana, CFO, CC

Certificate of Recognition - Outstanding Achievements in Recognizing Customer Service and Employee Partnership - April 13, 1995

Special Service Award - Recognition of the Development & Implementation of the ORS Interactive Facility Management Database System September 18, 1994, Daryl Paunil, Chief Team 2, DCB, DES

David Herion, M.D.
Chief Medical Information Officer (CMIO)



ACADEMIC DEGREES/CERTIFICATIONS

Medical Degree (1988) – The University of North Carolina School of Medicine, Chapel Hill, NC

Undergraduate (AB Chemistry) (1984) – The University of North Carolina, Chapel Hill, NC

Certification, American Board of Internal Medicine (1993-current)

RELEVANT EXPERIENCE

National Institutes of Health (NIH), Clinical Center (August 2008 – present)

CMIO, NIH Clinical Center (CC) (August 2008 – present)

Provides executive leadership to identify, initiate and produce enhancements to clinical care and research information management processes and systems. Establishes and builds relationships between DCRI and physicians, mid-level practitioners and clinical research teams in the Institutes and Centers (IC's), particularly around issues of CRIS and other clinical IT systems and information management practices. Serves as executive liaison between DCRI and the NIH CC Pharmacy Department and participates as a DCRI representative on a number of NIH CC Committees.

Attending Physician, NIH CC (June 2005 - present)

NIH, National Institute on Alcohol Abuse and Alcoholism (NIAAA), DICBR/LCTS (June 2005 – August 2008) - Staff Clinician

- Outpatient clinical research unit director
- Principal Investigator (06-AA-0121, 08-AA-0137)
- Associate Investigator (06-AA-0120, 06-AA-0129) - Analysis and design of information systems for safety and compliance data in translational drug development clinical research projects. Implementation and management of electronic data capture systems for clinical research (case report forms). Design and implementation of specimen storage and information tracking system. Design of data management system for heart rate variability measurement in clinical research.

Neuroscience Institutional Review Board member (December 2006 - August 2008)

MedData, Inc., Bethesda, MD (March 2001 – June 2005)

Project Support Lead for Clinical Research Database and Information Management Project at the NIAAA, DICBR/LCTS and Laboratory of Neurogenetics (LNG)

Oversight and supervision of the technical staff of NIAAA clinical research data repository (CDR).

Managed NIAAA data exchange from CC (CRIS and CDR) Created reporting system (Crystal Reports) from SQL Server. Review and analysis of NIAAA clinical data and data management systems and preparation of report to Director, CC as part of the Standards for Clinical Research project. Application programming, technical instrumentation assistance, selected data management consultation and workflow-information mapping for LNG.

NIDDK - Data Manager, Cystic Fibrosis Center (CFC) (March 2001- present)

- Manage CFC CDR. Execute data exchange between CC (CRIS and CDR), NIDDK (CFC CDR) and PortCF, the Cystic Fibrosis Foundation Patient Registry.

CLINICAL RESEARCH - Associate Investigator

- Diagnosis and Treatment of Patients with Cystic Fibrosis and Other Disorders of the Respiratory System and Pancreas (87-DK-0029)
- Urinary Vitamin C Loss in Subjects with and without Diabetes (04-DK-0256)
- Vitamin E Pharmacokinetics and Biomarkers in Normal and Obese Women (09-DK-0097)
- Associate Investigator (inactive)- 15 other protocols
- Principal Investigator (inactive)- 2 protocols

PROFESSIONAL TRAINING

Medical Fellowship -

- Liver Diseases Section, NIDDK (intramural) NIH CC, Bethesda, MD (July 1995 – October 2000)
- Laboratory of Clinical Studies, NIAAA (intramural) NIH CC, Bethesda, MD (July 1992 – July 1995)

Chief Medical Resident

- The Centre for Addiction and Mental Health (formerly, The Addiction Research Foundation), Toronto, Ontario, Canada (July 1991 – July 1992)

Medical Internship and Residency in Internal Medicine

- The University of Alabama Hospitals, Birmingham, Alabama (June 1988 – June 1991)

LICENSURE

- North Carolina Board of Medical Examiners License Registration # 19057 (1988- current)
- Maryland Department of Health and Mental Hygiene License Registration # M58874 (2004- current)
- Ontario College of Physicians and Surgeons (1991, inactive)
- Alabama Board of Medical Examiners License # 14797 (inactive) (1989, inactive)

PROFESSIONAL MEMBERSHIPS

- Healthcare Information Management Systems (HIMSS) (2008)
- American College of Physicians (ACP) (1991)
- American Association of Liver Diseases (AASLD) (1995, inactive)

PUBLICATIONS (SELECTED)

Book Chapters

Everhart J, Herion D. Hepatitis C (Biomedical Research Reports). San Diego, CA: Academic Press; c2000. Chapter 19. Hepatitis C virus infection and alcohol; p. 363-88.

Journal Articles

Herion D, Hoofnagle J. The interferon sensitivity determining region: all hepatitis C virus isolates are not the same. [comment]. *Hepatology* 1997; 25:769-71.

George DT, Gilman J, Hersh J, Thorsell A, Herion D, Geyer C, Peng X, Kielbasa W, Rawlings R, Brandt JE, Gehlert DR, Tauscher JT, Hunt SP, Hommer D, Heilig M. Neurokinin 1 receptor antagonism as a possible therapy for alcoholism. *Science* 2008;319:1536-9

(16 others, references available on request)

AWARDS

NIH Clinical Center Director's Award: Administration. (December 2012) Award for outreach to CRIS Users through mechanisms including training, CRIS Booth, weekly rounds and the development of the CRIS User & Prescriber Groups.

Joyce A. Yarrington
Chief, IT Budget and Capital Planning



RELEVANT EXPERIENCE:

Chief, IT Budget and Capital Planning, Department of Clinical Research Informatics, NIH Clinical Center. (November 2010 to Present)

- Supervisory and leadership tasks include planning of work and setting and adjusting priorities for government FTE and contractors. Mentoring, counseling, and working with subordinate staff on setting and meeting goals. Plan, formulate, present, manage, and execute multi-million dollar departmental budget using a variety of tools such as Microsoft Excel and NVision the online NIH Budget reporting system. Estimation, preparation, evaluation, and tracking of over 100 annual IT contracts, which include labor, support services, hardware and software maintenance. FAC-P/PM Level III and FAC-COTR Level III Certifications. COTR for multiple IT maintenance and labor contracts. Approve invoices based on validation of services performed ensuring they are meeting our standards. Plan, formulate, present, manage, and execute the CC IT Capital Equipment (CERC-IT) Budget that facilitates the life cycle replacement of commodity desktops, laptops, printers, copiers, servers, network infrastructure, and software.
- Plan, formulate, present, manage, and execute the CC Telecommunications budget, which includes the approval of adds, move, and changes for network and telephone lines, monitoring of communication's related costs. Routinely perform system analysis which included meeting with departments and users to gather requirements, reviewed current processes, recommended process change to improve work flow, developed budgets, created schedules, and work with departments to implement the changes.
- Formulation and submission of CC Capital planning and Investment Control (CPIC) budget and other IT focused HHS and NIH Data call requests. Compilation, validation, and annual submittal of the Clinical Center's OMB Exhibit 53 and OMB 300 forms using the HHS ProSight System.

Deputy CIO, Technical Operations, Department of Clinical Research Informatics, NIH Clinical Center, (October 2004 – November 2010)

- Management of more than 60 IT staff including 10 contractors. Duties include project management, direct oversight of clinical application support, end user customer support, data center operations, server and operating system administration, networking, asset management, IT security, custom applications, and database administration.
- Supervisory and leadership tasks include planning of work and setting and adjusting priorities for government FTE and contractors. Mentoring, counseling, and working with subordinate staff on setting and meeting goals.
- Strategic planning, implementation, testing, and quality control of the CC Information Technology Architecture.
- Plan, formulate, present, manage, and execute multi-million dollar departmental budget using a variety of tools such as Microsoft Excel and NVision the online NIH Budget reporting system.
- Estimation, preparation, evaluation, and tracking of over 80 annual IT contracts, which include labor, support services, hardware and software maintenance.
- Project Officer for several IT contracts. Approve payments based on validation of services performed

ensuring they are meeting our standards.

- Plan, formulate, present, manage, and execute the CC IT Capital Equipment (CERC-IT) Budget that facilitates the life cycle replacement of commodity desktops, laptops, printers, copiers, servers, network infrastructure, and software.
- Plan, formulate, present, manage, and execute the CC Telecommunications budget, which includes the approval of all adds, move, and changes for network and telephone lines, monitoring of communication's related costs.
- Routinely perform system analysis which included meeting with departments and users to gather requirements, reviewed current processes, recommended process change to improve work flow, developed budgets, created schedules, and work with departments to implement the changes.
- Formulation and submission of CC Capital planning and Investment Control (CPIC) budget and other IT focused HHS and NIH Data call requests.

Chief, Data Center Operations, Department of Networks and Applications, NIH Clinical Center. (April 2000 - September 2004)

Managed the NIH Clinical Data Center 24x7 Operations' including direct supervision of 15 FTE and 4 contractors on the networking, server, and operations teams. Responsible for making sure that the Clinical applications such as CRIS were in operation 24x7 with minimum planned and unplanned downtime. Expanded the data center from 30 NT and UNIX based servers with a combined storage capacity of 480 gigabytes to 383 Windows and UNIX servers, and over 30 terabytes of storage.

- Planned, formulated, presented, managed, and executed annual data center operations budget
- Planned, formulated, presented, managed, and executed the IT portion of the activation budget for the new Clinical Research Center (CRC)
- Implemented vendor maintenance and support contracts for all IT equipment and software to ensure 99.99% uptime on data center equipment to support operations 24x7
- Designed the CRC wired and wireless network architecture and participated in the network activation
- Managed the successful IT implementation of the Clinical Research Information System (CRIS)
- Designed, planned, and managed the \$1M upgrade of the CC core network and the implementation of switching technology for 140 LAN closets.
- Consolidated CC department based servers into the data center to provide a secure server environment with emergency power, enterprise backups, and trained system administrators for 24x7 support

AWARDS

2001, 2002, 2004 & 2005 - NIH Clinical Center Directors Award

2005 - CRC Special Individual and Team Awards

2005 - CRIS Implementation Special Award

TRAINING

FAC-P/PM Level III Certification, FAC-COTR Level III Certification & NIH Senior Leadership Program Certification

PROFESSIONAL MEMBERSHIPS

Health Level 7 Association, Healthcare Information and Management Systems Society & American Medical Informatics Association

Susan M. Houston
Chief Portfolio Officer



ACADEMIC DEGREES/CERTIFICATIONS

Masters of Business Administration, Management, University of St. Thomas; St. Paul, MN

Bachelor of Science in Nursing, Mercy College of Detroit; Detroit, MI

RELEVANT EXPERIENCE

Chief, Portfolio Office, NIH Clinical Center, Department of Clinical Research Informatics (January 2003 – present)

- Manages the full lifecycle of clinical, administrative and research applications within the Clinical Center. This includes initial request review, analysis and approval process, the implementation, operations and maintenance change/release management, through to disposition.
- Works closely with the Clinical Center IT Advisory Group who provides governance for IT programs, projects and initiatives.
- Manages and supervises the Enterprise Architecture, Project Management, Configuration Management and Software Test teams.
- Mentors and supports staff related to IT governance, project management, and Enterprise Performance Life Cycle (EPLC) frameworks within the department and Clinical Center.
- Provides Project Management for clinical and technical projects of various sizes and complexity.
- Developed and managed the Project Management Office including the project management methodology and project templates.

Project Manager, Information Services Division, Ascension Health (November 2000 – August 2002)

- Project management for projects that spanned multiple platforms/systems including AIX, NT, Oracle, SQL, Client-Server, Thin-client (Citrix), interfaces and applications of clinical documentation and pharmacy.
- Managed project teams including developers, system administrators, application specialists, interface developers and technical support staff. Also worked closely with ESC (Enterprise Support Center) during hand off of support calls after go-live.
- Conducted analysis of workflows and data flows.

Consultant, Healthcare Practice, SafeNet Consulting, (January 1999 – September 2000)

- Consultant to multiple clients related to information technology within & outside the healthcare arena including a major HMO, healthcare branch of county government and a telecommunications company.
- Managed a variety of projects with teams consisting of developers, system architects, data modelers, testers and business owners.

Lead Account Manager/Project Manager, Implementation Services, Summit Medical Systems, Inc., (January 1997 – December 1998)

Provided project management, implementation coordination and support

- Facilitated the successful implementation of 2 beta sites for new clinical product.
- Managed multiple projects implementing a variety of offered products from initial kick-off meeting through training and post-live support. Coordinated and assisted with training of clients.
- Created and Maintained Implementation Kits for various products. Implementation kits included overview of implementation tasks, goals and timeline. It also included instructions and requirements for interfaces, data conversions, installation, report generation and customizations of clinical systems.
- Functioned as interim Director of Implementation Services Department.

ADDITIONAL EXPERIENCE

Adjunct Faculty, University of Maryland Baltimore – School of Nursing (January 2006 – April 2008, September 2013 - current) ‘Information Technology Project Management’ for the Masters of Nursing Informatics program

Nurse Manager, Emergency Center, Methodist Hospital, HealthSystem Minnesota (1993 - 1996)

Project Manager, TDS Clinical System; Clinical Coordinator; Staff Nurse, Emergency Center, St. Joseph Mercy Hospital, (1988-1993)

Supervisor, Emergency Center, Pontiac General Hospital, (1986-1988)

RECENT PUBLICATIONS (SELECTED)

Houston, S. ‘Selection, Implementation, Support & Maintenance’ chapter in ‘Preparing for Success in Healthcare Information and Management Systems: The CPHIMS Review Guide’. Chicago: Healthcare Information Management & Systems Society, 2013

Houston, S. The Project Manager’s Guide to Health Information Technology Implementation. Chicago: Healthcare Information Management & Systems Society, 2011.

Houston, S. & Bove, L. Project Management for Healthcare Informatics. New York: Springer, 2007.

RECENT PRESENTATIONS (SELECTED)

‘Just The FACTS on Mentoring Novice Informatics Nurses’, ANIA Annual Conference, San Antonio, TX; May 4, 2013

‘Managing Business Expectations in an IT Project’, HIMSS Annual Conference, Las Vegas, NV; February 24, 2012.

‘Evaluating Outcomes, Telling the Right Story with Data’, the Measurement, the Last Frontier of Healthcare Projects’ HIMSS Pre-conference Workshop; Las Vegas, NV; February 19, 2012.

‘A Two Phased Approach to Evaluate the Success of HIT Implementations’, ANIA Annual Conference; Las Vegas; May 13, 2011

AWARDS

2004, 2005, 2007, 2009 & 2010 NIH Clinical Center Director’s Award Recipient

PROFESSIONAL ORGANIZATIONS

Project Management Institute (PMI)

Healthcare Information and Management Systems Society (HIMSS)

American Nursing Informatics Association (ANIA)

LICENSES/CERTIFICATIONS

Michigan RN License #4704128694 - Active

Project Management Professional (PMP) Certification from Project Management Institute

Board Certified in Nursing Informatics (RN-BC) from American Nurses Credentialing Center

Certified Professional in Healthcare Information & Management Systems (CPHIMS) from Healthcare Information Management & Systems Society (HIMSS)

Fellow Member (FHIMSS) of the Healthcare Information Management & Systems Society (HIMSS)

Susan Marie Martin, RN, BSN, JD
Chief, Security and Privacy Office



ACADEMIC DEGREES/CERTIFICATIONS

Juris Doctorate (1988) Georgetown University Law Center, DC
Bachelor of Science in Nursing (1978) University of Akron, Akron, OH

RELEVANT EXPERIENCE

Chief, Security and Privacy Office, Department of Clinical Research Informatics, NIH Clinical Center. (September 2008 - present).

- Provides strategic planning and leadership to CC ISSO and information security specialists to address security and privacy for existing and new CC IT Systems
- Provides strategic leaderships for the implementation of NIH IT Security Projects within DCRI and the NIH CC
- Serves as Privacy Coordinator for Warren Grant Magnuson Clinical Center, responding to all privacy inquiries from customers; investigating all security incidents involving PII; ensuring compliance with privacy awareness training requirements
- Provides consultation and analysis to procurement and CC IT implementation teams to ensure new system configuration is compliant with CC, NIH and HHS Information Technology policies and standards
- Facilitates development and annual review of Privacy Impact Assessments for CC IT systems and CC Third-Party Websites and Web Applications
- Provides consultation and analysis to Medical Records Department leadership
- Provides leadership and support to CC CIO
- Advises CC CIO and CC Executive Leadership on regulations impacting the security and privacy of the federal IT systems and electronic medical record

Senior Nurse Project Manager, Department of Clinical Research Informatics, NIH Clinical Center. (January 2007 – September 2008).

- Provided IT Project Implementation support in Warren Grant Magnuson Clinical Center
- Served as Project Manager for upgrade of CC Perioperative Information System
- Served as Project Manager for implementation/upgrade of other CC administrative applications
- Served as DCRI lead for development of requirements and procurement of CC Barcode Enabled Point of Care Testing System

Acting Deputy CIO, Department of Clinical Research Informatics, NIH Clinical Center. (April 2005 – January 2007).

- Provided strategic planning and leadership to the DCRI Clinical Operations Training and Support Team
- Provided leadership and support to CC CIO
- Served as Project Manager for implementation of the CC Perioperative Information System

Senior Nurse Project Manager, Department of Clinical Research Informatics, NIH Clinical Center. (December 2002 – April 2005).

- Provided IT Project Implementation support in Warren Grant Magnuson Clinical Center
- Served as Project Leader for development of CRIS Protocol Order Sets, Medication Work list and Nursing Department Orders
- Served on CRIS Project Management Team contributing to development of end user training and ancillary department orders

Chief, Department of Surgical Services, Department of Anesthesia and Surgical Services, NIH Clinical Center. (August 1998 – December 2002).

Provided strategic planning and leadership to the nursing and technical services in the Operating Room and Post Anesthesia Care Unit

Provided leadership and support to Chief, Department of Anesthesia and Surgical Services

Developed collaborative, working relationships with NIH surgeons, outside medical consultants, vendors and CC departments.

Responsible for the budget, clinical operations, HR, procurement and business operations in DASS

Nurse Manager, PACU and Surgical Services, Georgetown University Anesthesia Services Contract at NIH Clinical Center. (1995 – August 1998).

Provided strategic planning and leadership to the nursing and technical services in the Operating Room and Post Anesthesia Care Unit

Provided leadership and support to Chief of Georgetown Anesthesia Services Contract

Developed collaborative, working relationships with NIH surgeons, outside medical consultants, vendors and CC departments.

Responsible for the clinical operations, HR, and procurement operations in DASS

ADDITIONAL EXPERIENCE

Nurse Manager, Staff Nurse, and Per-diem Nurse in ICU, CCU and PACU in several academic medical centers in Michigan, Ohio and Washington, DC. (1978 – 1995).

Associate, Hogan and Hartson LLC. (June, 1988 – 1989).

Associate to Senior Partner in food, drug, medical device and agriculture practice group

Provided research to partner and support to medical device vendors preparing submissions to FDA for regulatory approval

AWARDS

- 2001 & 2006 - NIH Clinical Center Director's Administration Award Recipient
- 2001 & 2004 - NIH Clinical Center Director's Team Award Recipient
- 2000 - NIH CIO Certificate of Appreciation Award
- 1998 - NIH Clinical Center Nursing Department Director's Award

TRAINING

- Basic Project Officer
- American Heart Association, ACLS Instructor
- American Heart Association, BCLS and PALS Provider

PROFESSIONAL MEMBERSHIPS

- International Association of Privacy Professionals, Healthcare Sector
- American Society of Perianesthesia Nurses

2012-13 STAFF ACCOMPLISHMENTS

PAPERS

- Cimino, JJ, Farnum, L, Cochran, K, Moore, S, Sengstack, P & J. McKeeby. (2010). Interpreting Nurses; Responses to Clinical Documentation Alerts. Proc 2010 AMIA Fall Symposium, Washington, DC, 2010.
- Haerian K, McKeeby J, DiPatrizio G & JJ Cimino. (2009). Use of Clinical Alerting to Improve the Collection of Clinical Research Data. Proc 2009 AMIA Fall Symposium, San Francisco, CA, 2009: 218-222.
- Houston, S. (2011). The Project Manager's Guide to Health Information Technology Implementation. Chicago: Healthcare Information Management & Systems Society.
- Houston, S. (2013). Selection, Implementation, Support & Maintenance Chapter in Preparing for Success in Healthcare Information and Management Systems: The CPHIMS Review Guide. Chicago: Healthcare Information Management & Systems Society.
- Postal, S. & Griffioen, M. A. (2013, in press). The Value of Increasing the Number of DNP and PhD in Nursing. *The Maryland Nurse News and Journal*.
- Way, Cynthia & Jon W. McKeeby. (2012). Systems Thinking as a Team-Building Approach Reflections: The SoL Journal, Volume 11, Number 4, February 2012 , pp. 44-49(6). Publisher: Society for Organizational Learning.

PRESENTATIONS

- Briguglio, C & Defensor, R (2012, July). *A Comparison of User Satisfaction and Knowledge Test Scores Using Interactive and Non-interactive Computer Based Tutorials*. Presented at the Summer Institute in Nursing Informatics Conference, Baltimore, MD.
- Briguglio, C & Defensor, R (2013, February). *Interact or React: Media Learning and Student Satisfaction*. Presented at American Nursing Informatics Association webinar.
- Briguglio, C & Defensor, R. (2013, May). *Connecting the Dots: Taking the Learner from Classroom ... to ... Bedside*. Presented at the University of Pennsylvania Healthcare IT Roundtable, Philadelphia, PA.
- Briguglio, C & Postal, S (2011, July). *The Lifecycle of Training Materials: Teaching Clinicians the Use of a Clinical Information System*. Presented at the Summer Institute in Nursing Informatics Conference, Baltimore, MD.
- Carlson, Seth. (2013). *Implementing an Electronic Appointment Request with Enterprise Scheduling*. Allscripts Client Experience (ACE) Annual Conference – Chicago, IL; August 22, 2013
- Coffey, Tricia & McKeeby, Jon. (2013). Patient Portals: Using Leading Edge Technology to Manage the Delivery of Healthcare in a Patient-Driven Model. HiMSS National Capital Area Chapter. September 19, 2013. Rosslyn, VA.
- Defensor, Rubi. (2010). *Prescriber Clinical Documentation/ Physician Training for Documentation*. Eclipsys Client Connect Webinar. August 17, 2010.
- Houston, Susan & Kennedy, Ryan. (2011). *A Project Manager's Guide to Integration projects*. HIMSS Annual Conference; Orlando, FL; February 21, 2011.
- Houston, Susan. (2011). *Project Management: The Next Level – Managing Scope, Risks & Issues*. ANIA Annual Conference – Pre-conference Workshop; Las Vegas, NV; May 11, 2011
- Houston, Susan. (2012). *Managing Business Expectations in an IT Project*, HIMSS Annual Conference, Las Vegas, NV; February 24, 2012.
- Houston, Susan; Sengstack, Patricia. (2012). *A Two Phased Approach to Evaluate the Success of HIT Implementations*. ANIA Annual Conference; Las Vegas; May 13, 2011

- Houston, Susan; Sengstack, Patricia. (2012). *Evaluating Outcomes, Telling the Right Story with Data: Measurement, the Last Frontier of Health Care Projects*. Pre-conference workshop at HIMSS '12. February 19, 2012. Las Vegas, NV.
- Kennedy, Ryan. (2012, March). *Tailoring the EPLC: A Clinical Center Approach*. Project Management Center of Excellence, Bethesda, MD.
- McKeeby, Jon & Maloney, Tim. (2010). A 36 Hour Down: When the unthinkable happens. Allscripts/Eclipsys Annual Conference. San Diego, CA.
- McKeeby, Jon (2012). *IT Governance*. Allscripts/Eclipsys Annual Conference. August 19, 2012. Chicago, IL.
- McKeeby, Jon. (2011). NIH Clinical Center: An IT Perspective. HiMSS National Capital Area Chapter. April 2011. Rosslyn, VA.
- McKeeby, Jon. (2011). *Vetting Pharmacogenomics within an EHR*. Allscripts/Eclipsys Annual Conference. August 30, 2011. Nashville, TN.
- McKeeby, Jon; Joyce, Maria; Sengstack, Patricia. (2011). *Strategic Prioritization of IT Projects*. Allscripts/Eclipsys Annual Conference. August 30, 2011. Nashville, TN.
- Patel, Jharana Tina; McKeeby, Jon (2012). *Interfacing Contrast Medications from a Radiology System to SCM*. Allscripts/Eclipsys Annual Conference. August 18, 2012. Chicago, IL.
- Patel, Jharana Tina; McKeeby, Jon (2013). *Pharmacogenomics within an EHR*. Allscripts/Eclipsys Annual Conference. August 23, 2013. Chicago, IL.
- Postal, S. (2011, May). *Downtime preparedness*. Presented at the University of Penn. Allscripts User Group Roundtable, Philadelphia, PA.
- Postal, S.& Wight, J. (2012, April). *SCM 5.5 Upgrade: Lessons Learned*. Presented at the University of Penn. Allscripts User group Roundtable, Philadelphia, PA.
- Raju, Minnie & Kennedy, Ryan. (2011). *Implementing an Electronic ICU: What You Think You Know But Really Don't*. Allscripts Client Experience (ACE). August 2011. Nashville, TN.
- Raju, Minnie. (2012). *An ICU Transition: Electronic Documentation and the Clinical Data Viewer*. Allscripts Client Connect Nursing/Acute Care Share Group Webinar. June 5 and 21, 2012.
- Raju, Minnie. (2012). *Clinical Data Viewer-An ICU Transition to Electronic Documentation*. Healthcare IT Roundtable. January 5th, 2012. University of Pennsylvania. Philadelphia, PA.
- Raju, Minnie. (2013). *Clinical Data Viewer-An ICU Transition to Electronic Documentation*. Healthcare IT Roundtable. January 4th, 2013. University of Pennsylvania. Philadelphia, PA.

PANELS

Mobile Shared Service Models Panel. May 21, 2012. Government Information Technology Executive Council. Panel: Christopher J. Dorobek, William Lewis, Erna Giles Beverly, William Adams, Jon Walter McKeeby, D.Sc

American Council for Technology/Industry Advisory Council - ACT/IAC. 2012 ACT-IAC Small Business Conference. Needs of Federal CIOs. May 7 2012. Joe Klosky & Jon Walter McKeeby.

POSTERS

Briguglio, C & Defensor R (2010, July). *24X7 Access Requirement: Developing an Electronic Medical Record Online Training Program*. Presented at the Summer Institute in Nursing Informatics Conference, Baltimore, MD.

Defensor R (2010, July). *An Evaluation of Nursing Documentation Efficiency Prior to Implementation of Electronic Charting: An ICU Time-Motion Study*. Presented at the Summer Institute in Nursing Informatics Conference, Baltimore, MD.

DEGREES, AWARDS AND CERTIFICATIONS

Adams, Keith (2013, Aug). CompTIA A+ certification, Computing Technology Industry Association

Carlson, Seth. Masters Degree-Seeking student at University of Maryland in College Park in MS in MBA: Information Systems.

Chern, Chris. Certifications.

- Certified Information Systems Security Professional (#409271), 10/25/2011
- Certified Ethical Hacker, 11/30/2012
- Certified Network Defense Architect, 11/30/2012
- GIAC Reverse Engineering Malware (GREM), 1/24/2013

Dugar, Jothi. Master's Certificate in Project Management, ESI/GWU 2012.

Kingston, Joe. Certified Ethical Hacker, 8/30/2013

McKinney, Jeff (2012, Mar). Configuration Management Principles and Implementation Certification, University of Houston

McKinney, Jeff (2013, Jul). CMPIC® Master's Certification in Enterprise Configuration Management, University of Houston

Nghiem, Mindy. (2013, May). Project Management Professional (PMP), renewal.

Siwy, Chris. PhD Degree-Seeking student at George Mason University in Bioinformatics and Computational Biology

Wight, Judy. (2011, August). Project Management Professional (PMP).

CC DIRECTOR'S AWARDS

2010

Radiology DCRI Support Team: For exemplary IT support of Radiology and Imaging Sciences staff.

Devery Donovan; Theresa Eng

Patient Care: For the design and development of the Medication View Tab in CRIS, to meet the needs of physicians to have a direct view into the medications of their patients.

Gary DiPatrizio, PharmD

POIS Information System Implementation: Surgical Information System Implementation.

Tom Dawson; Susan Houston, RN, MBA; James Oseth

Research Lab Order Improvement: Improvement in ordering research samples and collection of research blood as well as increasing patient safety associated with research blood collection.

Seth Carlson

NIH Clinical Data Center Migration: NIH Clinical Data Center Migration

Mark Bradley; Doug Butters; Jason Chan; Dempsey Dunn; Alex Gregg; Barrett Grieb; Chris Klein; John Kocher; Todd Myrick; Brad Snakenberg; David Vinh; Judy Wight; Tadele Yenegeta.

2011

Jesse Ferguson Customer Service: For exemplary desktop support.

Mukesh Khatri

CDV Implementation Team: For creating and implementing a unique ICU electronic data viewer which enhances patient care and sets a national standard for facilitating ICU patient care.

Ryan Kennedy; Minnie Raju; Patricia Sengstack, DNP, RN-BC, CPHIMS

Outpatient Pharmacy Information System Team: For the design and implementation of an Outpatient Pharmacy information system and dispensing robot.

Stephen Blackwell, Mark Bradley, BS, Seth Carlson, BS; Jason Chan, BS; Gary DiPatrizio, Pharm D; Yenshei Liu, BS; Jeanne Preuss, BS, MT; Isolina Vargas, BS

Referring Physician Communication Technical Team: In recognition of efforts to enhance processes in CRIS to improve communication of medical information to patients' referring physicians.

Yulia Broydo; Seth Carlson, BS; Steven D. Moore, BS, EMSE; Michael Nansel, RN, BSN; Victoria Skahill, RN

2012

Administration: For providing outstanding leadership and technical support to the Clinical Center and Institutes through the provisioning of innovative clinical IT solutions.

Seth Carlson

Administration: For leadership for the CC IT Project Management Office in the activation of IT Clinical Solutions that support NIH CC and IC clinical needs.

Ryan Kennedy

Administration: For outstanding leadership of IT initiatives focused on the improvement of clinical care, patient safety and operational efficiencies.

Jon Walter McKeeby, DSc

CRIS Outreach Group: For outreach to CRIS users through mechanisms including training, CRIS Booth, weekly rounds and the development of the CRIS User's & Prescriber's groups.

Claudia Briguglio, MS, RN; Rubi Defensor, MS, RN; David Herion, MD; Lucia Menegussi, MS, RN; Susan Postal, MS, RN-BC; Minnie Raju, RN; Patricia Sengstack, DNP, RN-BC, CPHIMS; Alice Smyth, RN; Norma Street, RN

Migration of Sapphire to a More Robust Platform: For the update of the Sapphire Server involving the migration of almost 3,000 individual home directories and 170 group shares.

Arthur Cain; Barrett Grieb; Ryan Kennedy; Chris Klein; David Vinh

Jesse Ferguson Customer Service: For providing customer friendly and efficient CRIS and desktop service desk support.

Sandra Rodgers

Patient Care: For development of a Radiology Viewer to access CRIS Data efficiently

Frank Mickey

Pharmacogenomics Team: For implementing a clinical pharmacogenomics testing program to improve the safety of drug therapy.

Gary DiPatrizio, PharmD; Jon McKeeby, DSc.

Electronic Admission Consent Project Team: In recognition of efforts to implement an electronic mechanism for capturing signature on Clinical Center admission consent forms.

Seth Carlson; Frank Mickey

NIH DIRECTOR'S AWARDS

2010

NCAT Team: In recognition of outstanding contribution to test, document and upgrade the NIH Certification and Accreditation Tool (NCAT).
Victoria E. Ames

2009 Take Your Child to Work Day Program Coordinators: In recognition of exceptional performance and continuous support of the NIH "Take Your Child to Work Day" program.
Bertram Brown

2013

CC Data Transformation Initiative Project
James Pitts; Jon W. McKeeby, DSC

Staff Training

As an Information Technology organization it is important that DCRI staff are current with the latest technologies and the capabilities of the systems that we support. Table 4-5 reviews the DCRI Staff training opportunities for 2011-2013.

Each Supervisor provides a list of the training requests for Staff to the DCRI Executive that oversees their section. The list is reviewed and the goal for each staff member is to attend one job-related training item per year. Each section varies based on the number of request based on job function. Typically Systems and Monitoring has limited training request with the other sections varies. Attendance to conferences requires the staff member to submit a presentation and to present the presentation at the conference.

Table 4-5. DCRI Staff Training

Section	Number of Staff	FY 2011 Conferences	FY 2011 Training Classes	FY 2012 Conferences	FY 2012 Training	FY 2013 Conferences	FY 2013 Training
CIO	10	12	6	10	2	7	7
Security & Privacy Office	5	3	6	2	13	0	7
Portfolio Management Office	15	8	20	3	20	0	16
Project Management Office	8	7	11	2	15	0	9
Technical Architecture Team	4	1	8	1	5	0	5
Test Team	3	0	1	0	0	0	2
Clinical Informatics	22	14	14	11	15	4	16
Liaison Team	3	3	0	3	2	1	0
Clinical Build Team	14	7	11	6	7	2	11
Support/Training/Analysis	5	4	3	2	6	1	5
Technical Operations	62	5	69	7	43	1	25
Server Support and Data Center Operations	19	2	30	4	20	0	5
System Administration	10	1	16	3	11	0	5
Systems Monitoring	5	0	7	0	2	0	0
Unix Administration	2	1	5	1	3	0	0
Network Administration	2	0	2	0	4	0	0
Clinical Application	19	3	22	3	14	1	10
Interface Team	4	0	2	0	3	0	2
Clinical Database	7	2	9	2	7	1	7
Applications Team	5	1	5	0	2	0	1
Administrative Database	3	0	6	1	2	0	0
Technical Customer Support	24	0	17	0	9	0	10
Tier I Service Center	3	0	0	0	1	0	2
Tier II Support	16	0	13	0	7	0	5
Specialized Projects	5	0	4	0	1	0	3
Budget and Capital Planning	3	0	2	0	0	0	2
Program Support	2	0	2	0	0	0	1
Inventory & Property Management	1	0	0	0	0	0	1
TOTAL	117	42	117	33	93	12	73

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SECTION 4

KEY IT DRIVERS AND INFLUENCES FOR 2013-2014

DCRI Customers

Institutes and Centers

The NIH is composed of 27 Institutes and Centers (ICs) whose research activities extend from basic research that explores the fundamental workings of biological systems and behavior, to studies that examine disease and treatments in clinical settings, to prevention, and to population-based analyses of health status needs. DCRI supports this work via computerized systems such as CRIS and its various components that allow Institute staff to enter, retrieve and trend research data. Efforts to interface various IC systems with CRIS will continue in 2013/14, as appropriate, to provide a centralized system for clinical patient data. Proactive planning for this work is essential, given that it is time and resource intensive as well as highly complex.

Clinical Center Departments

The CRIS system and CRIS data is utilized by each department in the Clinical Center and IC as part of the intramural program. These include:

<ul style="list-style-type: none">• Nursing and Patient Care Services,• Office of the Director,• Critical Care Medicine,• Medical Records,• Imaging Sciences,• Transfusion Medicine,• Pharmacy,• Ambulatory Care Services,• Nuclear Medicine,• Perioperative Medicine,• Nutrition,	<ul style="list-style-type: none">• Rehabilitation Services,• Laboratory Medicine,• Pain and Palliative Care,• OMS,• Social Work,• Spiritual Ministry,• Medical Consult Service,• Pediatric Services.
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Many of these departments are broken into subspecialties creating additional unique customers. Each area presents unique needs and requests that must be coordinated, analyzed, designed, built, tested, taught, and implemented. DCRI continues to proactively work with our key departments to request any future planned IT activities that will require assistance from DCRI. It is hoped that this approach will reduce unexpected work and result in more efficient resource.

External Drivers

Advisory Board for Clinical Research (ABCR)

The purpose of the ABCR is to provide advice and guidance to integrate the vision, planning, and operations of the NIH intramural clinical research programs. It was created due to a key recommendation from the NIH Director's Blue Ribbon Panel on Intramural Clinical Research. The recommendation was to revise the NIH intramural clinical research oversight structure by creating a single high-level oversight committee to replace all existing governing bodies that have oversight responsibilities for intramural clinical research. It includes four main working groups: Research Opportunities; Operations and Planning; Finance; and Careers in Clinical Research.

OMB/HHS

The Office of Management and Budget and the Department of Health and Human Services have both recently issued mandates that have impacted DCRI and IT use in general at the Clinical Center. These mandates include the Federal Desktop Core Configuration or FDCC, Homeland Security Presidential Directive 12 (HSPD-12), and the Enterprise Performance Life Cycle (EPLC) for managing IT projects.

NIH CIO

As the CIO for the NIH attempts to standardize applications and processes across the organization, the impact to DCRI will be variable and possibly result in unexpected work. With 27 Institutes and Centers, all using some form of information technology, the CIO will undoubtedly strive to consolidate and centralize IT use via the NIH's Center for Information Technology (CIT).

Review and Advisory Boards

Information Technology Advisory Board (ITAG)

The mission of the ITAG is to plan, approve, prioritize, and direct CC initiatives to ensure that customer expectations for IT solutions are met, IT risks are effectively mitigated, and best value is achieved to meet clinical, administrative and IT needs. ITAG recommendations are presented to the Director of the Clinical Center.

Medical Executive Committee (MEC)

The Medical Executive Committee (MEC) advises the Clinical Center Director on clinical aspects of operations and develops policies governing standards of medical care in the Clinical Center. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives. Directives and mandates from this group can influence our clinical systems and require reprioritizing DCRI's work based on identified needs.

The Medical Executive Committee - Information Technology (MEC-IT)

This subcommittee is a branch of the MEC whose focus is on the Clinical Center's IT needs. This group was created to assist DCRI in prioritizing work related to some of the larger projects that involve a high level of complexity, require a significant amount of DCRI resource, and will need careful planning and management in order to be successful.

Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics Committee meets monthly to review issues related to all aspects of medication management. Oftentimes situations arise where a request is made for data to be retrieved from the CRIS system or for DCRI to determine if there is a technical solution to address an identified problem.

The Joint Commission

An independent, not-for-profit organization, the JC is the nation's predominant standards-setting and accrediting body in health care. DCRI is responsible for ensuring that the JC standards for Information Management are met. In addition, each year the JC publishes their National Patient Safety Goals. Many of these goals require the direct involvement of DCRI, whether it's to develop new functionality for our clinical systems or to provide data from the numerous databases that DCRI manages.

Clinical Fellows Committee/Clinical Fellows IT Advisory Group

Created in 2004 to serve as a communications venue for clinical fellows, this committee meets quarterly with Dr. Gallin. Membership includes clinical fellows representing all Institutes. In 2007, a subgroup was formed (Clinical Fellows IT Advisory Group) that meets monthly to address CRIS/IT issues. We anticipate that issues will arise at these meetings that will require DCRI to provide information and/or analysis for issue resolution options and to make system enhancements to CRIS.

Nursing Information Systems Committee (NIS)

The Nursing Information Systems Committee (NIS) meets monthly and consists of nursing representatives from all departments in the Clinical Center. They discuss issues related to CRIS and brainstorm solutions for improvement. This forum is also where nursing related system changes are brought forward for review, feedback and approval. Additionally, this meeting is a time of sharing and learning for these CRIS super users. Members from DCRI's configuration team attend these meetings to hear issues and provide information as required.

DCRI/CRIS STAKEHOLDER MEETINGS

CRIS User Group

Description: This is a combined meeting of the CRIS Prescriber Group and ICDAG, bringing together a broad user base from CRIS (see descriptions of the groups, below). This strategic planning meeting is used to identify a roadmap to review the requests made throughout the year and to agree as a group to the priorities for CRIS updates for the next 12 months. This group also provides an opportunity for the clinicians and the key departmental staff to communicate their various perspectives around clinical information management, including CRIS use, but also, importantly, the processes supported by CRIS. This has served as an important mechanism for mutual understanding that also has helped DCRI better evaluate configuration requirements for CRIS and ancillary department systems and processes.

Chair: Yaron Rotman, MD & Madeline Michael, RD

Membership: CRIS Prescriber Group (see below) and ICDAG (see below)

Meeting Frequency: Quarterly

CRIS Prescriber Group

Description: The group is comprised of clinicians (Physicians and Mid-level Practitioners) from several IC's who were appointed by their Clinical Directors. These practitioners are regular users of CRIS and ancillary systems in both the inpatient and outpatient settings. Additionally, several of the members are principal and associate investigators. They also cover some of the busiest clinical services in oncology, hematopoietic stem cell transplant, infectious diseases and immune disorders, as well as other subspecialties. The group provides input, advice and feedback regarding CRIS and other clinical IT systems that DCRI supports, with an agenda set by the Chairman and the CMIO. This meeting is also an important point of communication for DCRI to the IC's regarding projects, initiatives, etc. Importantly, individual group members have been liaisons and facilitators of other meetings and communications between DCRI and clinicians in individual IC's. Several examples of this include presentations to IC's about new features in the upgrade to SCM 5.5 in late 2011/early 2012 and meetings with IC's regarding their clinical workflows to help inform the Scheduling project currently underway.

Chair: Yaron Rotman, MD Staff Clinician/Clinical Investigator, NIDDK, LDB

Meeting Frequency: Monthly

IC Membership:	CC Membership
<ul style="list-style-type: none"> • David Adams, MD (Staff Clinician, NHGRI) • Christine Alewine, MD (Fellow, NCI) • Sanjeeve Balasubramaniam, MD (Staff Clinician, NCI) • Brooke Decker, MD (Fellow, CC/NIAID) • Khanh Do, MD (Fellow, NCI/MOB) • Ladan Foruraghi, NP (NHLBI) • Joan Han, MD (Staff Clinician, NICHD) • Christopher Heery, MD (Staff Clinician, NCI/MOB) • Theresa Jerussi, NP (CC) • Sid Kerkar, MD (Fellow, NCI/LP) • Christopher Koh, MD (Fellow, NIDDK) • Tanya Lehky, MD (Staff Clinician, NINDS) • Jason Levine, MD (Staff Clinician, NCI/POB) • Yaron Rotman, MD (Staff Clinician, NIDDK) 	<ul style="list-style-type: none"> • Seth Carlson (CC/DCRI) • Tricia Coffey (CC/MRD) • Gina Ford, RN (CC/OD) • Barry Goldspiel, PharmD (CC/Pharmacy) • David Herion, MD (CC/DCRI) • Laura Lee, RN (CC/OD) • Jon McKeeby, DSc (CC/DCRI) • Jharana Patel, PharmD (CC/Pharmacy) • Susy Postal, RN (CC/DCRI) • Minnie Raju, RN (CC/DCRI)

<ul style="list-style-type: none"> • Richard Sherry, MD (Staff Clinician, NCI/SB) • Tiffani Taylor, PA (NCI/ETIB) • Henry Wiley, MD (Staff Clinician, NEI) • Eleanor Wilson, MD (Staff Clinician, NIAID) 	
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CRIS Interdisciplinary Clinical Documentation Advisory Group (ICDAG)

Description: This meeting sponsored and facilitated by DCRI includes all departments and disciplines in the Clinical Center that enter clinical documentation in the CRIS system. It provides a forum to discuss electronic clinical documentation issues that may potentially impact all CRIS users. Ideas are generated and communication takes place amongst all disciplines in this meeting.

DCRI POC: Minnie Raju

Chair: Madeline Michael

Membership: Deputy CIO for Clinical System Informatics, DCRI’s clinical documentation configuration team, Representatives from Nursing, Nutrition, Social Work, Rehab, Department of Perioperative Medicine, Medical Records, Imaging Sciences, Spiritual Ministry, Department of Laboratory Medicine, Office of the Director and Respiratory Therapy.

Meeting Frequency: Monthly

Systems Solution Partners (SSP) Meeting

Description: Consists of all administrators of the ancillary computer systems that interface with CRIS (Lab, Radiology, Nutrition, etc). We review and discuss CRIS activities and issues that may potentially impact ancillary systems. The meeting reviews changes at a high level and provides time for information sharing across multiple topics.

Membership: A member from all Departments which interface with CRIS.

Almazan, Yvonne (NIH/CC/DCRI) Chair	Kaczorowski, Karen (NIH/CC/OPD)
Barnes, Tony (NIH/CC/DCRI)	Little, Nova (NIH/CC/SURG)
Brown, Dennis (NIH/CC/CCMD)	Herion, David (NIH/CC/DCRI)
Brown, Michael (NIH/CC/PHAR)	Martin, Susan (NIH/CC/DCRI)
Chen, Te (NIH/CC/DRD)	Mayberry, Helen (NIH/CC/NURS)
Conley, Boyd (NIH/CC/DTM)	Parada, Suzan (NIH/CC/OPD)
Dugar, Jothi (NIH/CC/DCRI)	Pitts, James (NIH/CC/DCRI)
Hendery, Michele (NIH/CC/MRD)	Row, Chung-Hee (NIH/CC/DLM)
Houston, Susan (NIH/CC/DCRI)	Yarington, Joyce (NIH/CC/DCRI)

Meeting Frequency: Monthly, 2nd Tuesday of the month.

Clinical Center Departmental Meetings

DCRI routinely meets with each department in the Clinical Center. These meetings are conducted to allow a two way exchange of information between the department and DCRI. They are an important forum to update departments on what is happening from a DCRI perspective and hear about their IT issues and potential IT projects.

Table 4-1. Clinical Center Department Meeting List

Department	POC	Frequency
Admission/Outpatient/Nursing	Minnie Raju	Weekly
CCMD	Jon McKeeby, Ryan Kennedy, Minnie Raju	Monthly
DLM	Jon McKeeby	Monthly
DRD	Jon McKeeby	Quarterly
DRD Departmental Meeting	Steve Bergstrom	Weekly
DRD IT	Jon McKeeby	Quarterly
DTM	Jon McKeeby	Monthly
MRD	Jon McKeeby	Weekly
Nutrition	Jon McKeeby	Quarterly
Pharmacy MRB	Dr. David Herion, Gary DiPatrizio, Victoria Skahill	Monthly
Pharmacy Working Group	Gary DiPatrizio, Victoria Skahill	Weekly
RMD	Jon McKeeby	Quarterly
Social Work	Jon McKeeby	Quarterly
DPM	Jon McKeeby	Quarterly

DCRI MEMBERSHIP IN NIH COMMITTEES

NIH CIO Information Technology Management Committee (ITMC)

Description: The ITMC is led by the NIH CIO with CIT Director and NIH OCIO and CIT Representation and the IC CIOs. The committee reviews NIH information technology issues that affect the NIH and is a decision making body.

DCRI Membership: CIO

Meeting Frequency: Monthly

Trans-NIH Biomedical Informatics Coordinating Committee

Description: The Committee, subsuming the existing Roadmap Committee on Informatics, serves as a forum to gather data and inventories of the numerous informatics programs, projects, and plans within NIH and other federal agencies. With this knowledge, the Committee can provide informed NIH representation in discussions concerning standards and terminologies at DHHS and with other agencies, especially concerning improvements in health care and health research.

Membership: CIO

Meeting Frequency: Quarterly

NIH mHealth Program.

Common Fund Remote Mobile and Wireless Health (mHealth) Research Recruitment and Data Platform

Description: To develop the capacity for efficient, scalable wireless and mobile health research using a common, remote research recruitment and data platform.

DCRI Membership: CIO

Chair: Wendy J. Nilsen, Ph.D.

CIO-SP3/CIO-SP3-SB Advisory Committee 2011-2012.

Description: Provided the desired oversight of the results of the technical reviews of CIO-SP3 and CIO-SP3-Small Business.

DCRI Membership: CIO

Membership: Jon Walter McKeeby - Chair, Stacy Charland, John Folkers, John Prue, Chris Ohlandt
The NIH Information Technology Acquisition Assessment Center (NITAAC) issued two solicitations for Information Technology services and solutions: Request for Proposal NIHJT2010001 entitled, Chief Information Officer-Solutions and Partners 3 (CIO-SP3); and, NIHJT2010002 entitled, Chief Information Officer-Solutions and Partners 3 – Small Business (CIO-SP3-Small Business). During calendar year 2011, the NITAAC Program has been intensely involved in the source evaluation and selection process for these solicitations, which is intended to result in the award of a series of Indefinite Delivery/Indefinite Quantity (ID/IQ) contracts that can be used by other federal government agencies to acquire a variety of information technology (IT) solutions for the next ten year period. These IT and solutions include health and biomedical-related IT services to meet scientific, health, administrative, operational, managerial, and information management requirements. The programmatic ceiling for each award is estimated at \$20 billion.

DCRI MEMBERSHIP IN CLINICAL CENTER COMMITTEES

NIH Clinical Center - Department Heads

Description: This group, facilitated by the Director of the NIH Clinical Center (CC), represents each department that resides within the CC and is a forum for communication, education and discussion of new business and current issues. Information technology is a frequent topic of discussion as DCRI supports each department's technical needs.

DCRI Membership: CIO; Deputy CIO

Meeting Frequency: Monthly

NIH Clinical Center - Business & Operations

Description: This group, sponsored by the Director of the NIH CC, reviews the financial and operational status of the CC and discusses current issues as well as future financial and resource investments – including IT investments.

DCRI Membership: CIO

Meeting Frequency: Weekly

Medical Executive Committee

Description: The Medical Executive Committee (MEC) - advises the Clinical Center Director on clinical aspects of operations and develops policies governing standards of medical care in the Clinical Center. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives. Directives and mandates from this group can influence our clinical systems and require reprioritizing DCRI's work based on identified needs.

DCRI Membership: CIO, Non-Voting

Meeting Frequency: Twice a month

Medical Executive Committee - IT Subcommittee

Description: This is a working group of the Medical Executive Committee that addresses IT issues that affect the Clinical Center. They assist in the prioritization of IT projects and initiatives for the CC.

DCRI Membership: CIO, CMIO, Chief Portfolio Office, Deputy CIO

Meeting Frequency: Quarterly

Clinical Center – Institutes/Centers Planning Meetings

Description: These meetings are facilitated by the Director of the NIH Clinical Center and involve discussions with Institutes that utilize the CC for patient research. This forum is a two way exchange for strategic planning. They provide an opportunity for the Director to disseminate information regarding current CC operations as well as a time for the Institutes to discuss various future plans that involve use of the CC.

DCRI Membership: CIO, Deputy CIO

Meeting Frequency: Meetings with each Institute (17 Total). Once a Year

Clinical Fellows Committee

Description: This group of Clinical Fellows meets quarterly to discuss a variety of topics that impact the delivery of care at the CC. They interact closely with the CRIS system and provide a valuable resource for suggesting enhancements to improve patient care.

DCRI Membership: CIO, CMIO, Deputy CIO

Meeting Frequency: Quarterly

Clinical Fellows Committee - IT Subcommittee

Description: This group is a subset of the Clinical Fellows Committee. It consists of a volunteer group of clinical fellows from several Institutes. This group is essential in providing feedback and input for CRIS changes.

DCRI Membership: CMIO, Deputy CIO
Meeting Frequency: Quarterly

Patient Advisory Group

Description: Members of this group serve as informal advisors to the Clinical Center director regarding issues of concern to patients. Former and current patients may be nominated for membership by NIH Institute directors. The Patient Advisory Group was originally convened in 1998 to facilitate planning for the Mark O. Hatfield Clinical Research Center.

Membership: CIO

Meeting Frequency: Twice a Year

CRIS Steering Committee

Description: The CRIS Steering Committee provides planning and budgetary oversight for the overall CRIS initiative. This group is represented by directors and administration from multiple Institutes and centers and has provided direction for the overall CRIS project. They are currently involved in discussions and oversight of the Biomedical Translational Research Information System (BTRIS) project.

DCRI Membership: CIO, Non-Voting

Meeting Frequency: Monthly

Clinical Care - Department Heads

Description: This group, sponsored by the Deputy Director of Clinical Care at the NIH CC, is comprised of Department Heads, whose areas provide clinical care to patients. This meeting provides a forum for communication, education and discussion of new business and current issues. Information technology is a frequent topic of discussion as DCRI supports each department's technical needs.

DCRI Membership: CIO

Meeting Frequency: Monthly

NIS – Nursing Information Systems

Description: This group serves as a liaison between DCRI and Nursing and Patient Care Services (NPCS) for the development, maintenance, and evaluation of clinical documentation in CRIS, the electronic medical record.

DCRI Membership: Deputy for Clinical Informatics, DCRI Nurse Analysts

Meeting Frequency: Monthly

NPC – Nursing Practice Council

Description: This council meets monthly and supports professional nursing practice and facilitates professional development through collective decision-making. Discussions at this meeting frequently include potential enhancements to the CRIS system.

DCRI Membership: Deputy for Clinical Informatics (or designee from Clinical Informatics team)

Meeting Frequency: Monthly

Clinical Issues/Patient Safety Committee

Description: Consists of an interdisciplinary team that addresses Joint Commission and Patient Safety standards throughout the CC/CRC. DCRI listens to issues and suggests potential technical solutions that CRIS may be able to solve to reduce the impact of current manual processes.

DCRI Membership: Deputy for Clinical Informatics

Meeting Frequency: Weekly

Medical Record Committee

Description: This committee meets monthly to review proposed additions to the medical record as well as discuss the current status of the transition to an all electronic medical record.

DCRI Membership: Deputy for Clinical Informatics; CMIO

Meeting Frequency: Monthly

Consult Service Committee

Description: This group is primarily comprised of physicians who provide consultative services to patients at the NIH CC. This meeting is a forum to discuss their various issues and processes affecting the service they deliver. Their services are ordered via the CRIS system and they utilize CRIS for electronic clinical documentation. DCRI is represented to listen to and address their various technologic needs.

DCRI Membership: CMIO

Meeting Frequency: Monthly

Pharmacy and Therapeutics Committee

Description: – This group meets monthly to review medication-related practices and policies in the Clinical Center. CRIS updates and reviews are a standing item on the agenda.

DCRI Membership: Pharmacy Expert, CMIO

Meeting Frequency: Monthly

DCRI COMMITTEES & MEETINGS

DCRI Configuration Control Board (CCB)

Description: The Configuration Control Board (CCB) reviews and recommends projects/initiatives to understand both the costs and benefits to the organization.

Membership: NIH CC CIO, Chief Medical Information Officer (CMIO), Chief Technical Operations, Chief Portfolio Management, Deputy CIO

Meeting Frequency: Once a month

Functional/Application Review Board (FRB)

Description: The Functional/Application Review Board (FRB) analyzes and recommends System Change Requests (SCRs) from the perspective of CRIS usability and operability.

Membership: Supervisor Build Team Chair, membership includes DCRI supervisors and subject matter experts from several teams such as CM, clinical applications, reports, interface, CRIS DBA, and the executive leadership team. **Meeting Frequency:** Weekly

Architecture/Technical Review Board (TRB)

Description: The Architectural/Technical Review Board (TRB) analyzes and recommends System Change Requests (SCRs) from a technical perspective to understand the impact on the hardware, network and servers within the NIH CC Data Center.

Membership: Enterprise Architect Chair, membership includes DCRI supervisors and subject matter experts from several teams such as custom applications, servers, clinical applications, desktop support, network, CITRIX, DBA and the executive leadership team.

Meeting Frequency: Weekly

Emergency System Change Request (EMR) Team

Description: The Emergency SCR Team was created to authorize and approve immediate implementation of an emergency change request when time is insufficient to convene a review board.

Membership: Membership includes the department's executive leadership and the leaders of the FRB and TRB. An emergency change is required to correct any issue affecting patient care or the availability of any system within the DCRI Data Center that arises outside of the scheduled update periods as described later under Release Management.

Meeting Frequency: As needed, all on-line

DCRI Weekly Check in: Resources Meeting

Description: This meeting is to provide status on key issues within the department regarding resource staffing and projects.

Membership: NIH CC CIO, Chief Medical Information Officer (CMIO), Chief Technical Operations, Chief Portfolio Office, Deputy CIO, Chief Security and Privacy and Chief of Budget and Contracts

Meeting Frequency: Weekly (Monday)

DCRI Weekly Check in: Budget Meeting

Description: This meeting is to provide status on key issues within the department regarding DCRI's budget.

Membership: NIH CC CIO, Chief Medical Information Officer (CMIO), Chief Technical Operations, Chief Portfolio Office, Deputy CIO, Chief Security and Privacy, Chief Budget and Contracts and DCRI's Administrative Officer

Meeting Frequency: Weekly (Wednesday)

Senior Leadership/Team Leaders Meeting

Description: This meeting provides a forum for all DCRI managers and leaders to discuss current issues impacting the department. It is a time for communication and information sharing from the NIH CC CIO

to the team and an opportunity for section leaders to share current status on their specific area and bring up any issues that may need discussion.

Membership: DCRI Executive Leadership team, DCRI's Administrative Officer, and all DCRI section leaders.

Meeting Frequency: Monthly (4th Tuesday)

CIO's Meeting

Description: This meeting includes top management in DCRI. It provides a forum for upper level discussions regarding high impact decisions and strategic planning for the department.

Membership: NIH CC CIO, Chief Medical Information Officer (CMIO), Chief Technical Operations, Chief Portfolio Management, Deputy CIO.

Meeting Frequency: Twice a month

DCRI Professional Development Meetings

Description: These monthly meetings have recently been instituted to provide ongoing education and continued growth and learning of our staff. Topics presented alternate between individual self-improvement concepts and technical information relevant to our daily work.

Membership: All DCRI staff are invited to attend.

Meeting Frequency: Once a month

New Request Review Meeting

Description: This meeting provides an opportunity to review any new IT project that has been requested over the last week. Projects are analyzed for the impact on the Clinical Center, the department and our end users. They are also discussed and prioritized using a quantitative scale that provides a priority score for the projects importance and its potential complexity and work effort. A decision is made determining the process to complete the request (O&M project, initiative, SCR or ITAG project) as well as when the request can begin based on available resources.

Membership: Chief Portfolio Office, Deputy CIO, Chief Technical Operations, Enterprise Architect

Meeting Frequency: Weekly

* Note – the meetings listed above include only those that have the potential to have an impact on the entire department. There are additional routine meetings held within each section that provide a forum for communication and ensure that operations and maintenance are kept running smoothly on an ongoing basis. Additionally, there are ongoing scheduled meetings for each project currently underway. These project meetings typically involve the key stakeholders and include a review of the project's current status as well as a review of action items and the work plan.

DCRI OUTREACH ACTIVITIES

CIO Newsletter

Description: The CIO Newsletter is a monthly broadcast email to the CRIS user community about CRIS capabilities and issues. It includes upcoming events that have the potential to impact CRIS users as well as short educational pieces to help users in their interactions with the system. They are posted on the CRIS website for reference and as of this writing; there have been 40 issues of the newsletter.

Editors: Josanne Revoir, Kelly Cochran, Chris Chern, Jothi Dugar

Frequency: Every Other Month

<http://cris.cc.nih.gov/news/index.html>

CRIS Alerts to Medical Staff and CRIS Users

Description: These email alerts provide critical information to CRIS users regarding impending system changes and system downtimes. These are necessary to maintain the integrity of clinical and research information and processes to insure the continuation of clinical care and research studies during the absence of available electronic/automated clinical systems (scheduled or unscheduled).

POC: Susy Postal

Frequency: On Demand

<http://cris.cc.nih.gov/procedures/downtime.html>

Rounds on Nursing Units and Outpatient Clinics

Description: A team from DCRI and Nursing and Patient Care Services (NPCS) conduct weekly CRIS rounds on patient care units, referred to as "Walking Wednesdays." Walking Wednesday's has proven to be a valuable source of information for DCRI and NPCS regarding CRIS problems and concerns. Nurses and physicians seize the opportunity to ask impromptu questions, discuss CRIS challenges, receive just-in-time instruction, or pass along a previously unknown problem.

Membership: Rubi Defensor, Bertram Brown

Meeting Frequency: Weekly

CRIS Booth

Description: DCRI sets up an educational booth quarterly in a high traffic area along with a Workstation on Wheels that displays the CRIS system. Our training team provides outreach by meeting and greeting CRIS users, demonstrating CRIS features, answering any CRIS questions, providing reference handouts – all in an atmosphere of fun with CRIS games and prizes offered.

Membership: Rubi Defensor, Frankie Smyth

Meeting Frequency: Quarterly

Disaster Preparedness Participation

Description: A small team from DCRI works as part of a collaborative partnership with the Bethesda Hospital Emergency Preparedness Partnership program. Activities include:

- Participating with disaster and emergency drills
- Developing a process in the event of communications failure or other emergency

Frequency: On Demand and/or Scheduled

Advanced CRIS Training

Description: Customized 2 hour CRIS training sessions are now offered to CRIS users to help provide education that goes beyond standard training. These sessions include: creating custom patient lists, developing personal filters, navigating the system more efficiently and other topics that attendees request the instructors to cover.

Frequency: Monthly or as requested by CRIS users (ie, CC Departments or NIH Institutes)

Research Informatics Student Mentoring

Description: DCRI provides students and interns the opportunity for orientation to the department and to our work practices that support our mission. Students assigned to DCRI have many opportunities to become involved in most aspects of a system life cycle (analysis, planning, designing, building, testing, training, implementing, evaluating and maintaining). We mentor them through various program requirements and ensure that their experience is valuable and that they leave with new skills.

Examples include:

- Students in the Master's Nursing Informatics program at the University of Maryland, Baltimore. A clinical practicum with DCRI is typically where they conduct their capstone project in their final semester of the program.
- Summer Interns – we typically have three to four summer interns who are required to complete a research project and present their findings on NIH Research Poster Day.
- Clinical Research Management Sabbatical Program – this is a new program where DCRI will be participating in the mentoring of clinical investigators to provide an opportunity for these individuals to develop and broaden leadership skills in order to provide an optimal environment for conducting clinical research. DCRI will be providing learning experiences in the area of clinical informatics as it relates to clinical research.
- Medical Record Department's Graduate Students – we provide a clinical informatics component to their training experience at the NIH Clinical Center.
- **Frequency:** On Demand and/or Scheduled

Extra-Departmental Educational in-Service

Description: DCRI training staff routinely reaches out to CRIS users and others interested in how we capture clinical research electronically. Our team provides information, educates and shares information about CRIS functionality and how our various systems work as an entity. Audiences are varied in terms of discipline and come from within and from outside the Clinical Center.

Examples Include:

- Provided various in-services and educational sessions for several Institutes regarding Clinical Documentation in CRIS as we transitioned to an electronic format for progress notes.
- Provided CRIS demonstrations to various interest groups and discussed the role of informatics in a clinical research setting (NIH Animal Hospital in Frederick, Ireland Delegates, INOVA CNO, NIEHS remote branch in North Carolina, Medical Record Department's Graduate Students)
- Participated in the Department of Nursing's Education Fair with a CRIS Booth
- Presented informational session at Information Technology Management Committee (ITMC) meetings including topics such as Configuration Management, Project Prioritization and Activation Planning.
- **Frequency:** On Demand and/or Schedule

SECTION 5

MANAGEMENT CONTROLS

IT Governance

At the time of the 2009 Operational review DCRI had over 120 project/activity items on a list. These items all required resources from more than one team and the estimation for the required work was a minimum of 40 hours per item. The list was daunting and the prioritization was conducted by the CIO using a home-grown prioritization model taking into account resource and financial requirements and patient safety and prioritization. The prioritization was not vetted outside of DCRI and there was little stakeholder involvement in the prioritization of projects.

As a result the main recommendation from the 2009 Operational review was the development of the Information Technology Advisory Group or ITAG. This section reviews the Mission, Responsibilities, Membership and the Project Review Process of the ITAG.

Mission of ITAG

To plan, approve, prioritize, and direct CC initiatives to ensure that customer expectations for IT solutions are met, IT risks are effectively mitigated, and best value is achieved to meet clinical, administrative and IT needs. The ITAG is advisory to Dr. Gallin who makes the final decision.

Responsibilities

The ITAG shall have the following areas of responsibility:

- Determine and consistently apply criteria for prioritizing and recommending CC IT investments to the CC Director, with consideration of both cost and opportunity. Ensure that all projects selected are in alignment with the CC Strategic Operating Plan.
- Review and approve significant resource, scope and/or schedule changes to IT initiatives as they arise. Re-evaluate and prioritize, as needed.
- Determine and consistently apply criteria to measure the effectiveness of initiatives, post implementation. Ensure that lessons learned are evaluated and incorporated into future planning.

Meeting Schedule

- The ITAG meets on a quarterly basis:
 - March and September meetings are to review and recommend a slate of projects
 - June and December meetings are to receive progress reports and discuss emergent needs
 - Benefits of this schedule:
 - Remains flexible to accommodate emergent needs (i.e. mandates, patient care needs, small projects)
 - Allows ITAG to take a more strategic approach to reviewing projects and align with annual budget
 - Prioritization scores can be viewed across a slate of projects, versus one-by-one

Projects Governed by ITAG

Project requests are reviewed by ITAG if they involve:

- New capital IT equipment
- New functionalities, interfaces or applications
- Significant application upgrades (versions)
- New CC IT investments that require implementation and on-going support

ITAG Review Process

- Project Requests are complete by Departments and submitted electronic to the ITAG Review Committee.
- All requests are reviewed more closely to identify the project scope, impacts, resource requirements and financial requirements and the request is fully documented.
- Requests are reviewed by the ITAG Review committee to determine the next steps, require review by the ITAG committee based on the defined criteria, or if they are operations and maintenance to be managed internally by DCRI.
- A list of all the projects and the request documentation are sent to the ITAG Committee membership for review.
- The ITAG committee scores the projects online based on strategic alignment and impact to patient care. The DCRI staff provides a score for the work effort.
- At the quarterly meeting the results of the voting is reviewed and the project stakeholder is invited to discuss any issues, concerns or to answer questions regarding the request.
- The committee's recommendations are discussed with Dr. Gallin for final approval.
- The final decision is communicated to the stakeholders and approved projects are provided to DCRI for scheduling.

Membership

1. **Leighton Chan—Chair; Chief, Rehabilitation Medicine Department, CC**
2. Jim Cimino; Chief, Laboratory of Informatics Development, CC
3. David Bluemke; Director, Radiology & Imaging Sciences, CC
4. Tricia Coffey; Chief, Medical Records Dept., CC
5. Eric Cole; Senior Administrative Officer, DDCC
6. Sherry Sheldon; Transfusion Medicine, CC
7. Barry Goldspiel; Deputy Chief, Pharmacy Dept., CC
8. Deb Kolakowski; Nursing Director, Advanced Practice & Outcomes, NPCS, CC
9. MEC Rep – Rick Davey, M.D., NIAID
10. CRIS Users Group Reps (only one voting) – Yaron Rotman, M.D., NIDDK
11. NIH CIO Rep—Renita Anderson)
12. Yang Fann, Ph.D., NINDS Intramural IT and Bioinformatics Program (non-voting)

Key Staff/Expertise:

1. Sue Houston; Chief, Portfolio Office, DCRI, CC
2. Daniel Rinehuls; Deputy CFO & Chief, Office of Financial Resource Mgmt, CC
3. Chris Epinger; Financial Analyst, Office of Financial Resource Mgmt, CC
4. David Herion; Chief Medical Information Officer, DCRI, CC
5. Ryan Kennedy; Project Management Office, DCRI, CC

Administrative Support:

1. Rachael Schacherer; Special Assistant to the CFO, CC
2. Daniel Hobbs, Special Assistant to Chief, Rehabilitation Medicine Dept, CC

Ex Officio:

1. Jon McKeeby, Chief Information Officer, CC
2. Maria Joyce, Chief Financial Officer, CC
3. Laura Lee; Special Assistant to Deputy Director for Clinical Care, CC

Accomplishments as of August 2013

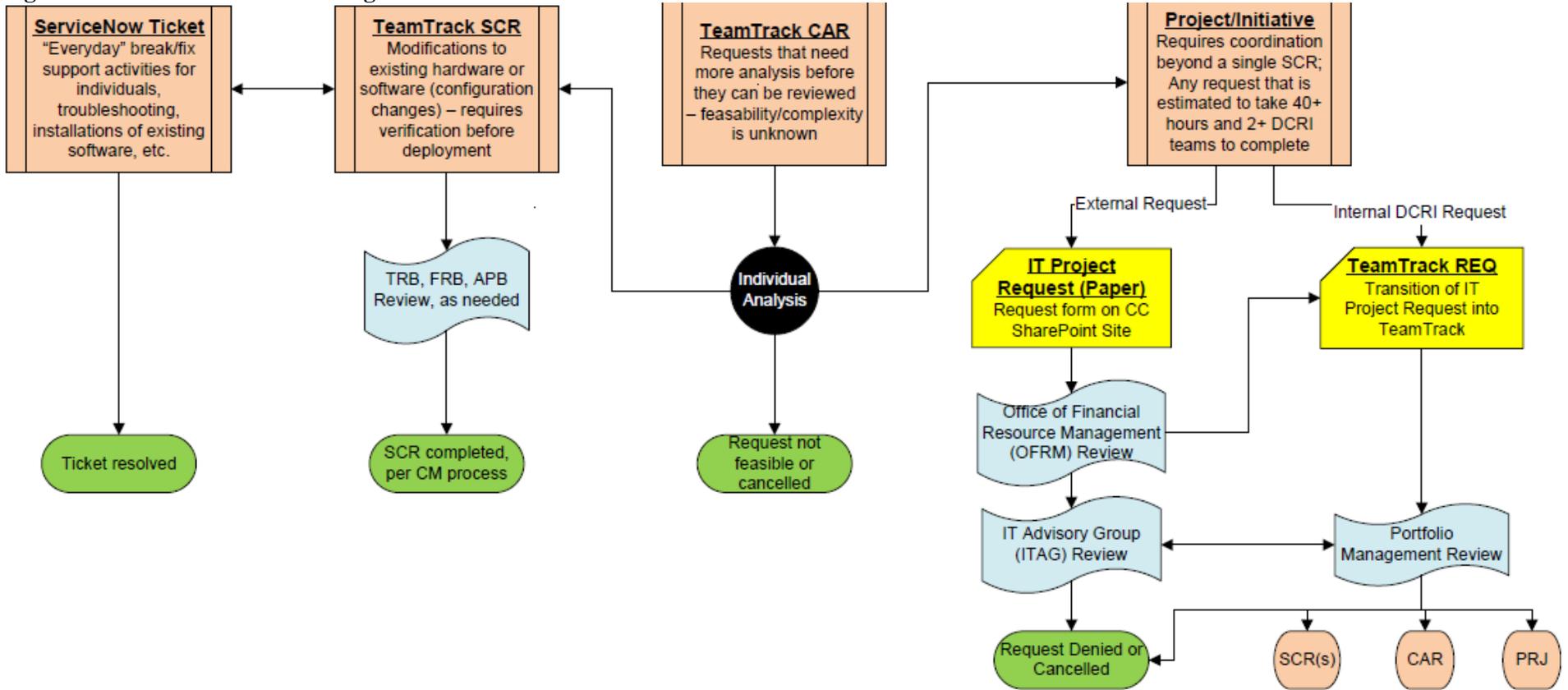
- 25 project requests have been submitted since the inception of the ITAG
 - All have been reviewed by the ITAG with recommendations made to Dr. Gallin
 - 23 of the 25 projects requests reviewed were approved, and have been or will be scheduled for implementation
 - 2 projects had their scope adjusted during the ITAG discussion to achieve quicker implementation while still meeting the needs of the requestors—Radiation Oncology Branch ARIA-CRIS interface; OCRTME Fellow Application system.
 - 2 of the 25 project request reviewed was not approved for implementation—OSFM Arts Inventory Database was denied and CCMD Ultrasound is on hold for evaluation of other options.
- To date, all projects that the ITAG has approved have been implemented, are in-progress, or have an estimated start date. The committee does provide direction on how to fit new high priority, or mandated requests into the schedule.
- CC leadership, specifically those on the ITAG committee, have a better awareness of DCRI's operational challenge of meeting growing IT demands across the hospital, within our limited staffing resources.
- In addition, the ITAG has been made aware of upcoming initiatives such as Insurance Billing Pilot, which may impact DCRI's slate of projects. When necessary, the current ITAG prioritization process can be leveraged to review and make recommendations on which projects need to be delayed or stopped to accommodate critical organizational requirements.

Workload Management

All work within DCRI is classified as either Service Ticket, System Change Request (SCRs), a Project or an Initiative. Figure 7-1 reviews the quick reference for how each item is processed.

1. Projects/Initiatives, that require ITAG review or not, are scheduled within DCRI once approved. DCRI manages projects/initiatives following the DCRI Project Management Methodology that will be described below in the project management section.
2. SCRs contain technical descriptions of proposed system changes. These are used by system administrators to document their work, coordinate between teams, allow for higher level technical review, and provide for management approval. Project managers use SCRs to task IT teams, track progress and coordinate project implementations. The documentation is produced or updated daily by staff and reviewed weekly by the Functional and Technical Review Boards. The management of SCRs will be reviewed below in the Configuration Management Section.
3. Service Tickets contain the information necessary for effective management of an IT service desk. Customers use the system to request service, IT technicians and managers use it to understand problems, communicate with the customer, and track progress. Service tickets are track primarily break-fix-install issues. The management of Service tickets will be review in below in the Desktop Service Model Section.

Figure 5-1. DCRI Workload Management Process



Project Management

The Office of Management and Budget (OMB) and the Congress have set high standards for the management and performance of information technology (IT) investments within the Federal Government. In order to sustain a formalized and consistent approach for managing all projects within the NIH Clinical Center's Department of Clinical Research Informatics (DCRI), the Project Management Office (PMO) has developed the methodology described below. The methodology utilizes several concepts defined by the Project Management Institute (PMI), while still maintaining compliance with the OMB-mandated Enterprise Performance Life Cycle.

DCRI PROJECT MANAGEMENT OFFICE (PMO)

The DCRI Project Management Office (PMO) is the centralized location for the coordinated management of projects within DCRI. The PMO provides project managers as well as support, mentoring and education. All projects or initiatives supported by the PMO follow a standard methodology and utilize standard tools, such as the Tracking of Initiatives and Projects system (TIPs), SharePoint and document templates. The PMO also assists with the analysis of new project requests and is responsible for the Combined Project List and monthly Project Dashboard.

PROJECT MANAGEMENT METHODOLOGY

Definition of a Project

The DCRI recognizes an IT project as having the following distinct characteristics:

- It requires over 40 hours of staff time to complete, post-analysis
- It is temporary
- It produces a unique product, service or result
- It is done for a specific purpose
- It has interrelated activities or tasks
- It becomes progressively more detailed as the request is better understood
- It has a distinct and planned outcome/deliverable

Requests that take less than 40 hours to complete are considered general Operations & Maintenance (O&M) and fall under the DCRI Configuration Management process.

If a request is determined to fall under the characteristics of a project, the DCRI Project and Portfolio Management Office (PPMO) assigns it into one of four categories: EPLC Project, O&M Project, Initiative, or Department-Run Project.

An EPLC Project

- Is as any project that must start at Phase 1 of the EPLC framework
- Includes all stage-gate reviews required by HHS
- Is led by a project manager from the DCRI PMO

An O&M Project

- Is any project for a system that is already in Phase 9 of the EPLC framework
- Is led by a project manager from the DCRI PMO

An Initiative

- Is any request that can be managed through multiple System Change Requests (SCRs) – *see the Configuration Management Plan for additional detail on SCRs*

- Is led by a DCRI staff member, typically external to the DCRI PMO
- Has a PMO representative assigned as a consultant in a non-leadership role

A Department-Run Project

- Is any request whose management is coordinated by a department external to DCRI, and is usually owned by the department that made the original request
- Requires little to no personnel from DCRI
- Has a PMO representative assigned as a consultant in a non-leadership role

Regardless of the type, all NIH CC IT projects are monitored by the DCRI PMO and are reported to the NIH CC leadership (CIO and CFO) on a monthly basis.

Process Overview

The project management methodology adopted by the DCRI PMO should be followed for every project and initiative managed through this department. Smaller projects, or initiatives, may be managed by Project Leaders, but a Project Manager should always be assigned to assist and support the Project Leader as needed.

Each project will be managed through the standard staged approach, from Initiating through Planning, Executing and Controlling to Closing. The amount of time spent on each phase will vary based on the size and complexity of the project.

All IT projects, including new applications (purchased or developed), will be evaluated for the need to follow the HHS EPLC process. This process is required for all Clinical Center projects meeting the EPLC requirements documented in the EPLC Framework, even when DCRI is not involved, and may be tailored based on the uniqueness of each project. Regular status reports for all EPLC projects are required and will be submitted by the Chief, PMO or designee.

Roles & Responsibilities

The following roles should be defined before the project is started. The project/initiative lead is responsible for ensuring that all of these roles have an appropriate resource defined.

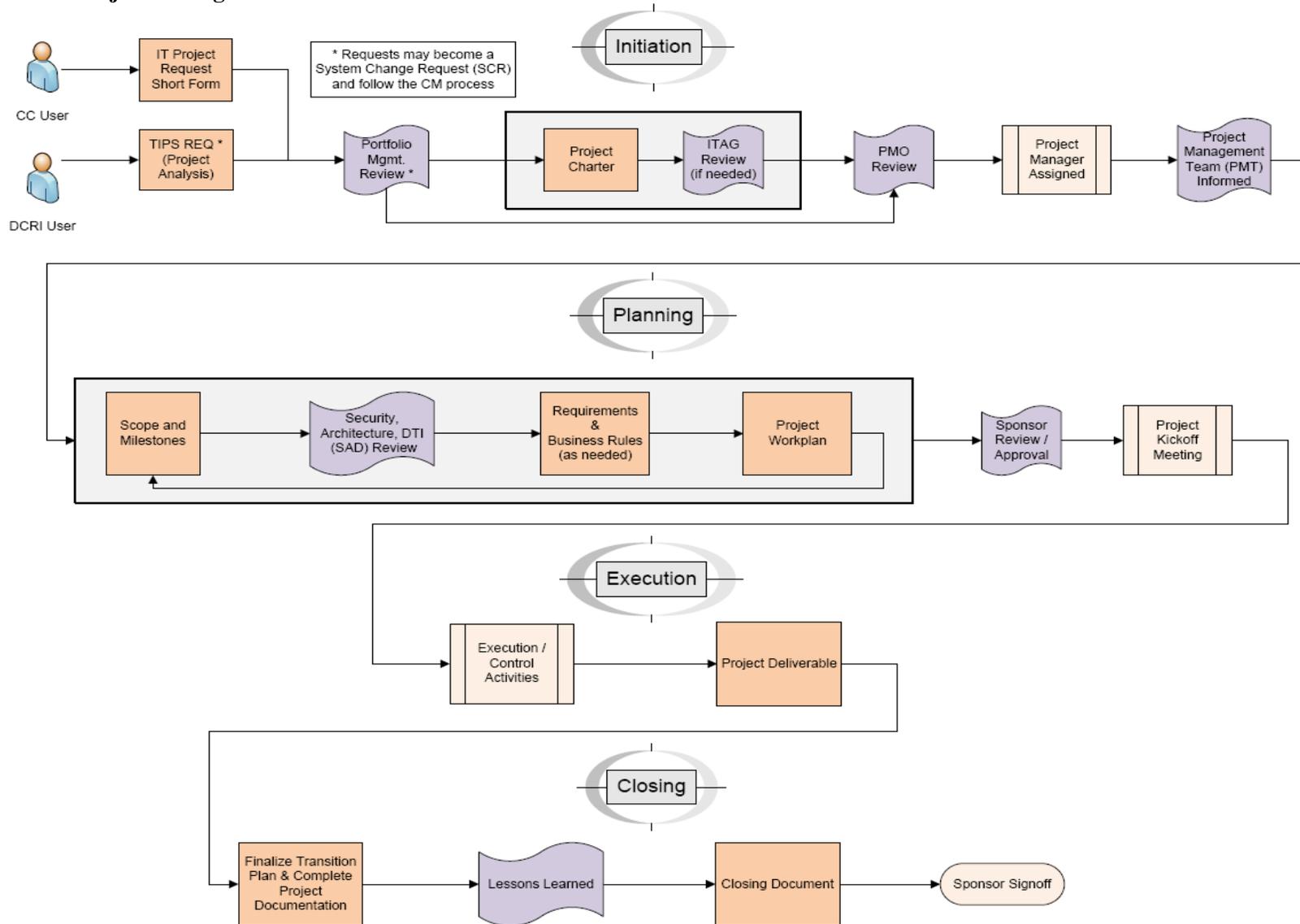
The project/initiative leadership includes:

Table 5-1. Project Roles

Role	Responsibility
Chief, PMO	Provides leadership, direction and support for all projects ensuring they have clear goals, objectives, timelines and measurable milestones. The Chief oversees the development and management of the Project Office as well as the education, coaching and mentoring of all staff related to project management. The Chief provides a regular status update for all ongoing projects to the CIO. This person may also assume the Project Manager or Project Leader role on projects.
Project Manager	Manages cross functional teams responsible for delivering defined project outputs on time, within budget and with quality results. Responsible for all project related activities as identified below in Initiating, Planning, Executing and Controlling and Closing phases. Ensures all project documentation is completed. When working with external vendors who have assigned project managers, the responsibilities contained within this document may be shared between both PMs.
Project Leader	Leads a sub-project group and represents the team within the larger project.

Role	Responsibility
	Responsible for all project related activities, as identified below, for their portion of the larger project. Ensures all project documentation is completed for their portion of the larger project. This person may also assume the Project Manager role on smaller projects, or initiatives. A project leader would never assume this role for an EPLC project.
Project Sponsor	Responsible for owning the project from conception to completion and is the final authority with regard to decisions on the project scope, change requests, resources, and other project-related activities. The sponsor usually includes one sponsor from DCRI to represent the technical side of the project and one sponsor from the requesting department or IC to represent the functional, business, or clinical side of the project.
Contract Officer	Responsible for all contract negotiation and coordination along with maintaining all contract documentation.
Project Consultant	When a project request is submitted, the Project Consultant works with the requestor to draft and finalize a Project Charter. The consultant is always a member of the PMO, but that person is not necessarily responsible for the ultimate management of the project/initiative, should it be approved.

Figure 5-2. DCRI Project Management Process Flow



The main steps with in the process are defined below:

Initiation

- IT Project Request
- Statement of need & justification
- Estimated resources required (DCRI & Other)
- Estimated costs & if available
- High level project definition
- EPLC evaluation
- Project prioritization

Planning

- Define scope
- Obtain project team
- Define work plan
- Complete project management plan i.e. Communication, implementation and testing plans
- Obtain approval from Sponsors
- Kick-off meeting

Execution and Control

- Complete all work defined in planning phase
- Project change control
- Risk management
- Communication
- Project deliverable validation
- Activation (go-live)

Closing

- Acceptance of project deliverable by Sponsors
- Hand-off to post-live support
- Documentation of lessons learned
- Project completion & approval
- Archive all project documentation

Tools used as part of the project management process include Tracking of Initiatives and Projects System (TIPs) which is a project management structure within our TeamTrack Configuration Management System, SharePoint and MS Project. TIPs is used to manage:

- Project request & prioritization
- Project scope & approval
- Project change request, impact analysis & approval
- Project risk identification & management
- Project issue identification & management
- Project completion & approval

Figure 5-3 on the next page shows a screen shot displaying a portion of the template in TeamTrack TIPs used for entering a project scope.

Figure 5-3. TIPs Project Screen

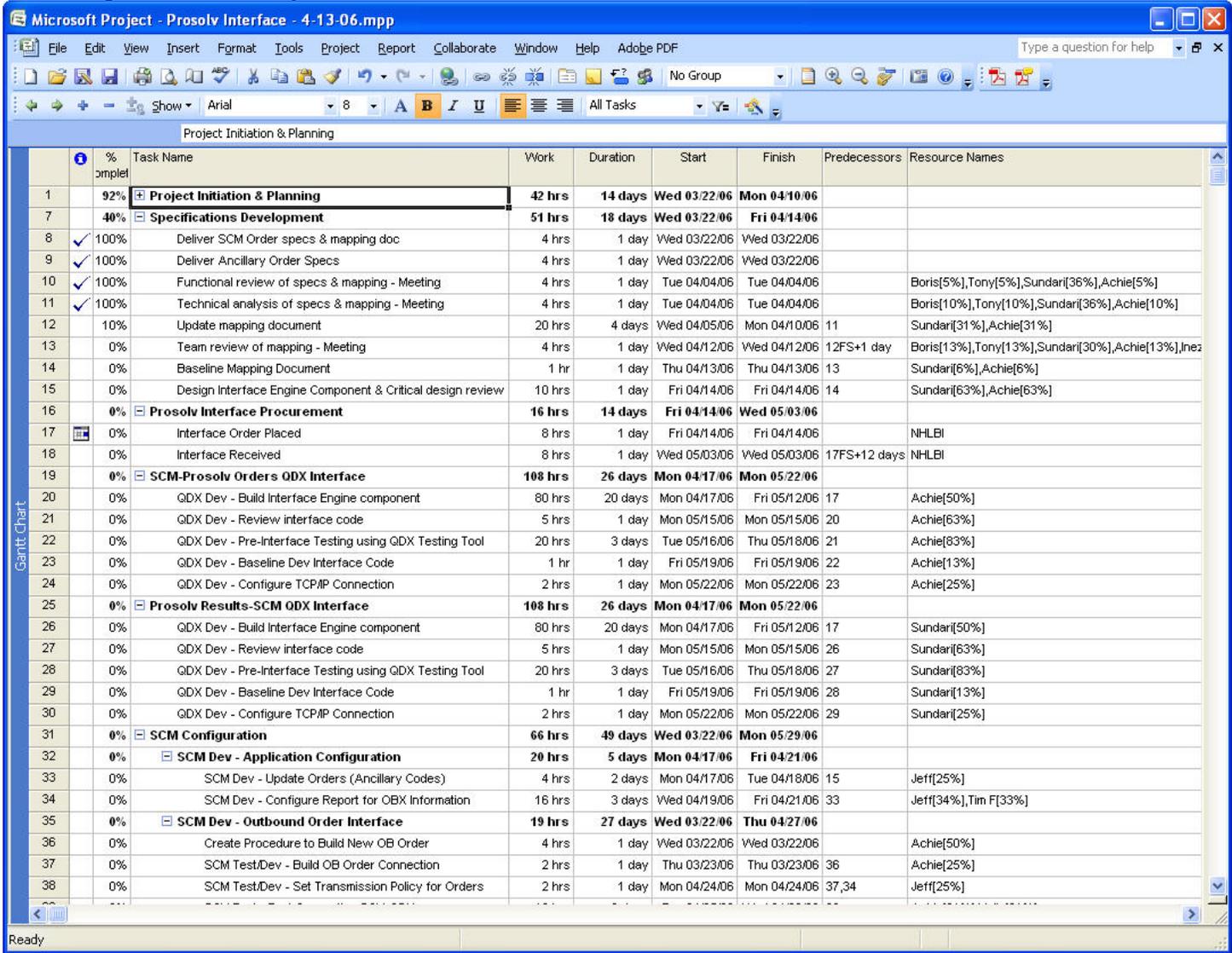
The screenshot displays the TeamTrack™ TIPs Project Screen. At the top, there is a navigation bar with tabs for TIPs, CRIS SCRs, CRIS CARs, TT Requests, Testing Incident, and BTRIS. Below this is a secondary navigation bar with Home, Submit, Search, Reports, Settings, and an ID Search field. The main content area is divided into sections: Current Assignee: (Auto), Justification (a large text area), User Fields (containing dropdowns for Project Manager, DCRI Sponsor, CRIS Team Members, Project Management Officer, Team Leader, Non-DCRI Sponsor, Non-CRIS Team Members, Scope Approval Status, Architecture Review, Architecture Reviewer, Security & Privacy Review, Security & Privacy Reviewer, and checkboxes for PIA and SORN Required), and Advanced Fields. The bottom of the window shows a Done button.

Microsoft SharePoint can be used to host web sites that access shared workspaces, information stores and documents. DCRI utilizes SharePoint to provide communication and collaboration among the project team where each project has their own site which includes:

- Project documentation
- Project calendar
- Project work plans & milestones
- Project team roles & contacts
- Project communication plan
- Project issue identification & management
- Project decisions
- Project links and discussion
- Team meeting minutes

A sample of a work plan completed in MS Project is shown in Figure 5-4.

Figure 5-4. MS Project Plan



On the following pages is a Gantt Chart listing the start and estimated activation for each project and a portion of the Project List. The project list is updated monthly showing the demographics and team resources required for each project.

See Appendix E: Project Management Methodology for a complete review of the process followed for Project Management. See Appendix F for a list of the Current Projects and Appendix G for a review of the OD Dashboard.

Table 5-2. Current Project List

ID	Title	Description	Lead	Phase	Est. Start	Est. Activation	Major Issues/Risks & Impact to Project	Accomplishments in June, 2013
PM-168	3rd Party Reimbursement	Implement a billing system for billing patient's insurance for non-protocol activities	Maria Joyce	Plan	11/15/2012	1/1/2014	<ul style="list-style-type: none"> • Risk: The timeline for implementation is fixed 	<ul style="list-style-type: none"> • Began review of proposals for TPR integration contract • Finalized SOW for billing vendor
PM-171	TPR: Insurance Collection	Third Party: Develop a process to collect insurance information from all patients in all outpatient clinics, admissions, and RADIS/PVCS areas.	Lucia Menegussi	Plan	4/17/2013	Dec, 2013	<ul style="list-style-type: none"> • Potential scope change: The electronic documentation of the HIPAA consent form may become embedded within the insurance 	<ul style="list-style-type: none"> • Procured and tested sample card scanner • Completed initial prototype of insurance collection form
PM-170	TPR: NPI Update	Third Party: Update the NPI number in Sacred and CRIS	Mindy Nghiem	Initiate	6/17/2013	Dec, 2013	<ul style="list-style-type: none"> • Risk: Need to determine how to collect missing NPIs - individual vs. NIH representative application for the NPI 	<ul style="list-style-type: none"> • Conducted initial meeting with project stakeholders to determine project objectives • Completed a draft copy of the
PM-172	TPR: Diagnosis/IMO & Medical Necessity	Third Party: Implement Allscripts IMO and determine how to link diagnosis, medical necessity, problem lists, and health issues to TPR.	Mindy Nghiem	Initiate	5/23/2013	Jan, 2014	<ul style="list-style-type: none"> • Risk: There is limited CC knowledge of how Diagnosis, Medical Necessity, Problem Lists, and Health Issues need to be conveyed to a third party biller 	<ul style="list-style-type: none"> • Began discussions with Allscripts for IMO resource • Obtained documentation and software for IMO
PM-173	TPR: Segregation of Billable Data	Third Party: Develop a process to identify billable data from research data, and update systems accordingly.	Ryan Kennedy	Initiate	3/25/2013	Nov, 2013	<ul style="list-style-type: none"> • Risk: There are several options to completing this request, so the project scope is still under development 	<ul style="list-style-type: none"> • Conducted initial meetings with project stakeholders • Began review of protocol order sets for protocol mapping

Configuration Management

According to the Institute of Electrical and Electronics Engineers (IEEE) Standard 610, configuration management (CM) is:

A discipline applying technical and administrative direction and surveillance to identify and document the functional and physical characteristics of a configuration item, control changes to those characteristics, record and report change processing and implementation status, and verify compliance with specified requirements [3].

Configuration management ensures that changes to an information system are applied in a controlled fashion, which reduces the risk of negatively impacting other system areas. It starts by defining and establishing a system baseline and ensures that all subsequent changes are controlled through a formal but efficient approval process.

The DCRI Configuration Management Plan (CMP) documents the processes and procedures used to identify, analyze, implement and track changes to the CC IT systems in an organized and controlled manner. The CMP applies to all information systems at the NIH Clinical Center that are supported by DCRI along with multiple CC Department supported systems. The plan describes the CM roles, responsibilities and activities that ensure effective management and control of changes to commercial off-the-shelf (COTS), custom developed systems, and their associated hardware.

Information system configuration is managed through a program of complementary, ongoing activities:

- Configuration Item Management
- Configuration and Release Management
- CRIS-Sunrise Custom File Management
- Hotfix Management

Change Control Boards (CCB) includes multiple review boards within DCRI and review boards in several CC departments that support their own systems. These boards have the decision-making authority to review and approve or reject System Change Requests (SCRs) that are submitted to modify a system, or hardware, that has an established baseline. There is also a process defined for approval of emergency SCRs outside of these meetings. The overall responsibility of the CCBs includes the following:

- Discuss and define the optimal approach for implementing process changes
- Discuss and decide the disposition (approve, deny, defer) and prioritize SCRs
- Discuss and decide the appropriate release cycle for SCRs

The Change Control Boards involved in the CC Configuration Management processes are as follows;

Technical Review Board (TRB) - DCRI

Reviews all SCRs and potential modifications to the CC IT infrastructure and meets weekly

Functional Review Boards (FRBs) - DCRI

Reviews all SCRs and potential modifications to CRIS-Sunrise and its integration with other systems and meets weekly

Architecture Planning Board (APB) – DCRI

Reviews and discusses potential modifications to the CC IT architecture along with defining the future IT Architecture Road Map and meets weekly

Pharmacy Review Board – CC Pharmacy and DCRI

Reviews all pharmacy related SCRs and potential modifications to CRIS-Sunrise or CRIS-Medication Management systems and meets weekly

Configuration Control Board (CCB) - CC Departments

These CCBs review all SCRs and potential modifications to their departmental supported system (i.e. Surgery-POIS, Radiology and Imaging Services-RIS/PACS). They have the authority to push a SCR to one of the DCRI CCBs if appropriate. The meeting schedules of these groups vary between the departments and are based on need.

Other groups that have the authority to review and submit SCRs or have SCRs deferred to for review, are listed below. The changes they review have the potential impact to multiple departments, units, or CC policies and procedures.

Information Technology Advisory Group (ITAG)

Reviews all CC IT Project Requests and provides recommendations the CC Clinical Director

Nursing (NIS and NPC)

Reviews all nursing related requests and submits those they approve

Interdisciplinary Care Documentation Advisory Group (ICDAG)

Reviews all clinical documentation requests and submits those they approve

SCM Hotfix Review Team - DCRI

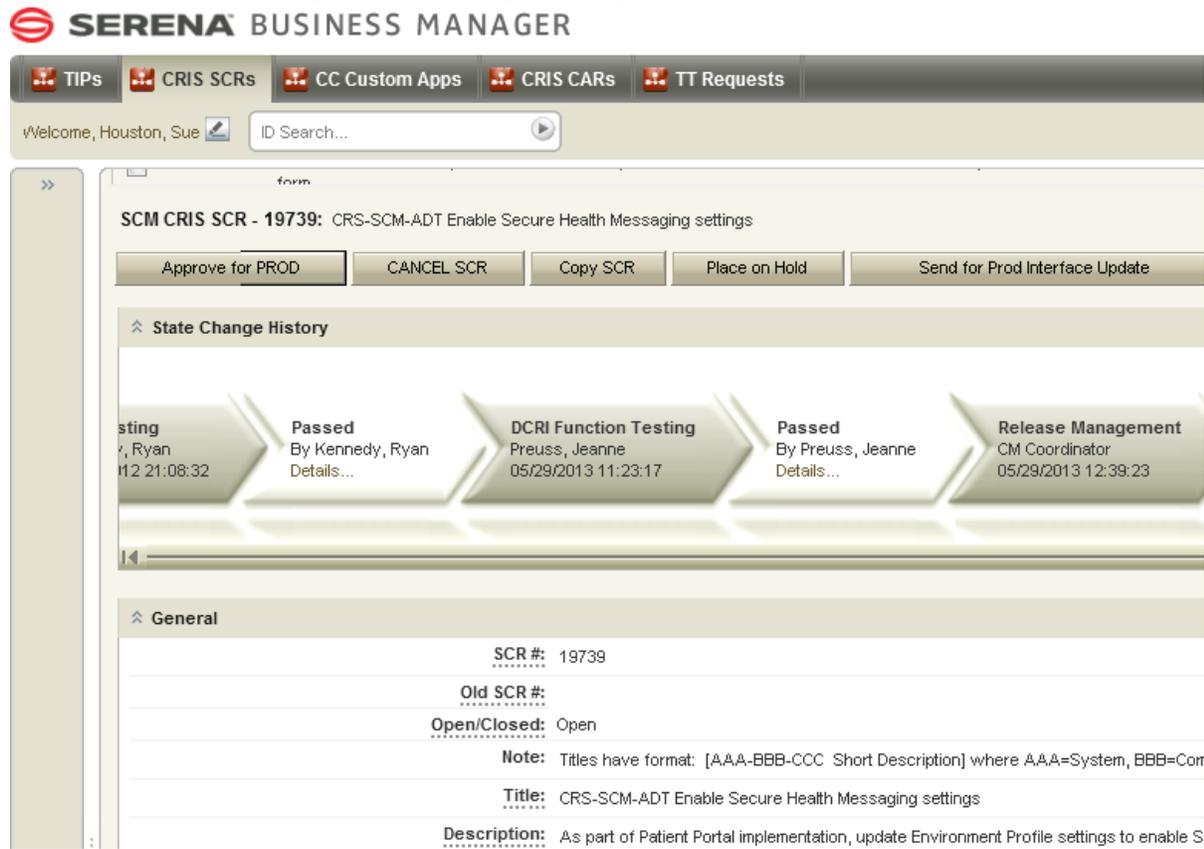
Reviews all vendor-supplied hotfixes for SCM and components, evaluates and makes recommendations for implementation on routine or urgent basis.

The DCRI Change Management process involves;

- Analysis of a formal request for a change
- Approving changes before implementation
- Release management
- Tracking changes through completion
- Reporting and statistics

The two main tools used as part of the Configuration Management Process include Serena Business Manager and the CM Outlook Calendar. Serena Business Manager provides a mechanism to manage the workflow of the CM process from the change request to production validation following the release management process..

Figure 5-6. DCRI Configuration Management System



To ensure changes are coordinated across the control boards, the Configuration Management Outlook Calendar is used. The CM Outlook Calendar contains all of the activities for each month and includes all activations of DCRI Projects, implementations of CRIS Releases and all infrastructure changes.

Figure 5-7. DCRI Configuration Management Calendar



See Appendix H: Configuration Management Methodology for a complete review of the process followed for Configuration Management.

Testing Methodology

The importance of effective testing cannot be over emphasized. Without rigorous testing in each of these four areas, system errors, loss of data and unhappy users are likely. Each Project, System Change Request, Application Configuration and System Migration has an associated test plan that is executed through the release management cycle, after the change is implemented in development/test environment and then validated once migrated to production.

Phases of Testing

Table 5-3. Description of Some of the Test Types

Test Type	Description
Unit testing	To verify the configuration of each item and to ensure that it is configured correctly. An item may include an order form, orderable item, security group, order set, or a report.
Function testing	To verify that the software's components operate as intended.
Integration testing	To verify that the applications and interfaces perform properly with each other in the planned production environment.
Regression testing	To ensure that the installation of a fix does not disrupt the original functionality of another part of the system. As part of all releases a standard script that tests multiple aspects of the system is performed ensuring that all aspects of the system work as expected.

See Appendix I for the Testing Methodology.

Standard Operating Procedures

A standard operating procedure (SOP) is a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. DCRI has developed multiple SOPs to support the ongoing maintenance and operations of our various systems to ensure a standard approach that reflects best practices. Table 5-4 reviews a list of SOPs developed by DCRI to manage every day Operations and Maintenance functions. Table 5-5 provides the list of SOPs specific for the configuration, testing, administration, maintenance to maintain CRIS.

Table 5-4. List of General SOPs and Policies

100% Prescriber Online Training	Non-CRIS Data base Management (Sybase, etc.)
Access Control	Printers Supported by DCRI
Active Directory (CC Domain & OU in NIH Domain)	Project Management
Audit & Accountability	Release Management
CA Tool Management	SCD Imaging
Change Management	Security & Data Center
CITRIX Server Administration Maintenance	Secure Sockets Layer (SSL)
Clinical Application Support Center	Secure-ID Administration
Data Center Operations Security	Server Administration – UNIX
DCRI Communication & Management Escalation	Server Administration & Operation
Desktop Support	Server Backup & Recovery
Disaster Recovery Master Plan	Server Monitoring
Firewall	Surplusing Govt Equipment
Hosting Label Printers Outside of Clinical Center	System & Comm Protection
Logical Print Location Configuration	Test Plan
Media Protection	Windows Server Hardening & Security

Table 5-5. List CRIS SOPs and Policies

CRIS Access Control Policy	CRIS SCM Application Troubleshooting
CRIS Analysis Request Process (CAR)	CRIS SCM Build Process
CRIS Ancillary Number Creation	CRIS SCM Building Order Sets Protocol, Non-Protocol, Lab & Pharmacy Order Sets
CRIS Audit & Accountability Policy	CRIS SCM Clinical Documentation Configuration & Maintenance
CRIS Configuration Management Policy	CRIS SCM db Troubleshooting
CRIS Configuration Management Security	CRIS SCM Express Load Unloads
CRIS Contingency Planning Policy	CRIS SCM Hot Fix Management & Deployment
CRIS Contingency Planning	CRIS SCM Item Info Roll-out
CRIS Core Storage Assignment Change SOP	CRIS SCM Item Information Updates Related to an SCR Release
CRIS Core User Account Management Policy	CRIS SCM Label Printer Troubleshooting
CRIS Core User Account Management	CRIS SCM New Locations within SCM
CRIS Data Center Operations Policy	CRIS SCM Order Browse Configuration & Maintenance
CRIS Eclipsys Remote Access to SCM Policy	CRIS SCM Order Forms & Orderable Items
CRIS Firewall Policy	CRIS SCM Order Results
CRIS Identification & Authentication Policy	CRIS SCM Order Security Configuration
CRIS Identification & Authentication	CRIS SCM Report Creation
CRIS Incident Response Policy	CRIS SCM Report Deployment
CRIS Incident Response	CRIS SCM Reports
CRIS System & Services Acquisition	CRIS SCM Starting the SCM Application
CRIS Lab Label Printer Troubleshooting	CRIS SCM Training Environment Maintenance
CRIS Maintenance Security Policy	CRIS SCM User Dictionary
CRIS Media Protection Policy	CRIS Security Awareness & Training Policy
CRIS MS Updates for Clinical Servers	CRIS Security Awareness & Training
CRIS Patient Merges	CRIS Security Certification & Accreditation Policy
CRIS Personnel Security Policy	CRIS System & Information Integrity
CRIS Personnel Security	CRIS Physical & Environmental Protection Policy
CRIS Physical & Environmental Protection	CRIS System & Services Acquisition
CRIS Printing	CRIS Technical Operations Service Policy
CRIS Privacy Policy	CRIS Training
CRIS Security Maintenance	CRIS User Account Management Policy
CRIS Security Planning Policy	CRIS Recommended AIX Server Security Standard
CRIS Security Planning	CRIS Recommended Database Server Customized Security Hardening Standard
CRIS Security Risk Assessment Policy	CRIS Recommended Domain Controller Customized Security Hardening Standard
CRIS Security Risk Assessment	CRIS Recommended Member Server Customized Security Hardening Standard

SECTION 5

SYSTEM CONTROLS

TECHNICAL ARCHITECTURE PLAN

The CRIS Technical Architecture Plan (TAP) describes the current NIH Clinical Center IT environment, and sets out the principles, standards, and conventions to align development efforts with the organization and program’s business vision. In addition, the TAP provides the technical basis for the IT strategy for the CRIS Program.

Version 1.0 was updated based on the CRIS Project and finalized 2004. The Table of Contents is shown in Table 5-1. The TAP is available through the Chief Information Officer and Chief, Department of Clinical Research Informatics.

Table 5-1. Technical Architecture Plan Version 1.0 Table of Contents.

Executive Summary	4.3 Application Architecture
Section 1—Introduction	4.4 Technology Architecture
1.1 Release Notes	4.5 Security Architecture
1.2 Background	Section 5—Standards, Conventions & Best Practices
1.3 Benefits to CRIS	5.1 Business Process
1.4 Purpose	5.2 Data and Database Management
1.5 Architecture Domains and Layers	5.3 Application Development
1.6 CRIS Technical Architecture Plan Contents	5.4 Technology
Section 2—Principles, Constraints & Assumptions	5.5 Security Guidelines
2.1 Architecture Design	Section 6—Migration Plan
2.2 System Design	6.1 Gap Analysis
Section 3—Current State Architecture	6.2 Implementation Options
3.1 Business Architecture	6.3 Projects Portfolio
3.2 Data Architecture	6.4 CRIS Transition Strategy
3.3 Application Architecture	6.5 Technology Insertion Strategy
3.4 Technology Architecture	6.6 Data Migration Strategy
3.5 Security Architecture	Section 7—Architecture Coordination & Maintenance
3.6 Issues With Current Architecture	7.1 Architecture Review Board
Section 4—Future State Architecture	7.2 Architecture Maintenance Plan
4.1 Business Architecture	7.3 Technical Architecture Repository
4.2 Data Architecture	

Version 1.0 of the CRIS Technical Architecture Plan (TAP) emphasized the cyclic and incremental nature of the planning process. The implementation and integration activities of the four years since the issuance of Version 1.0 have provided insight and information which allows the TAP to refine its view of the destination architecture and the process necessary to reach that destination.

Version 2.0 of the TAP starts by identifying our environmental constraints and risks; then identifies our goals in respect to the CC Technical Architecture. The TAP reviews the teams and control boards used to DCRI Operational Review

manage the technical architecture along with the processes and documentations used to enforce the desired technical architecture for the CC. The draft of TAP Version 2.0 was completed August 2013.

Environment Technical Constraints and Risks

The TAP identifies our primary technical constraints and risks as

1. Increasingly complex IT systems
2. Increasing system customizations
3. Increasing inter-system dependencies
4. Increased training requirements
5. Increased upgrade complexity
6. Multiple version of same technology
7. Reduced budget authority
8. Increased customer expectations

TAP Technical Goals

The TAP identifies our technical goals as:

1. Reduction in the number of technologies
2. Standardization with-in the same technology
3. Retirement of old systems
4. Identification and publication of dependencies
5. Virtualization of system
6. HA, DR and Continuity of Business Plans for all critical systems by 2014
7. HA and DR for 25% or remaining systems in 2013, 50% in 2014, 75% in 2015

TAP Technical Guidelines/Principles

TAP incorporates architectural principles, constraints, and assumptions based on the Enterprise Architecture (EA) concept of integrating ever-improving IT products, applications and systems.

- Architect all systems and interfaces to ensure that clinical research protocols are handled in the COTS packages.
- Design/configure all CRIS applications to expedite Computerized Prescriber Order Entry and reduce medical errors. Replace paper workflow with electronic data workflow.
- Maximize use of COTS applications. Design the architecture to integrate both COTS and custom developed solutions.
- Do not assume 100 percent COTS. Provide an integrated enterprise architecture and development environment that ensures integration between COTS, newly developed and existing production solutions.
- Create an architecture that supports loose rather than tight coupling between major applications. Architect a message-oriented middleware layer to provide platform and data-independent access methods for data exchange and information control.
- Capture information at the source. Avoid multiple entries of data. Use interfaces from System of Record to other systems.
- Separate Online Transaction Processing (OLTP) data stores and Online Analytical Processing (OLAP) or Business Intelligence data stores, designing each to optimize support updates and queries, respectively.
- Protect data as a valuable enterprise asset.
- Share data with all users with a credible need to know; data does not belong to an individual.
- Log and/or audit all data access to patient data. Data privacy must be a major factor in designing any and all user access to data.
- Build a stable interface infrastructure. The interface infrastructure enables the smooth exchange of information. Ideally all interfaces use a limited set of stable and standard services.

- Ensure that all client application software providing user interface services is compatible with the Standard Clinical Desktop (or its replacement), and that users can switch between applications without adverse effects. This will enable the use of standard desktop images, which allows for more effective deployment and maintenance of client-side application software.
- Establish a security framework so all stakeholders have the same perspective on security needs. Involve all security stakeholders early in the process to ensure all factors have been considered and facilitate security evaluation and certification.
- Leverage security best practices, balanced with unique NIH CC needs, to create a robust security approach. Implement Single Sign On capability so that users can switch between applications without having to login multiple times.
- Give preference to open systems standards over proprietary standards.
- Leverage the strong intranet infrastructure in the NIH CC as a key element of the enterprise architecture. Clearly communicate its capabilities to each application project. Organize the infrastructure into a centralized service-level-based platform.

TAP Technical Teams

The main teams and control boards used to review the technical architecture are reviewed below:

- **Architectural Planning Board (APB):** The APB is chartered to plan future architecture technologies, review the technical aspect of proposed systems, and approve the EA documents. This board is chaired by the CC IT Enterprise Architect, meets weekly and consists of senior IT subject matter experts.
- **EA Virtual Team (EA-VT):** The EA-VT is chartered to review and document any new or upgrading IT system. This team has primary responsibility for creating and maintaining the baseline EA documentation. The EA virtual team participates in a weekly phone conference call and includes representatives from the following teams: server, network, DBA, desktop support, interface, Citrix, PMO analyst and developer groups.
- **Technical Review Board (TRB):** The TRB reviews all changes to the CC IT Infrastructure, schedules IT upgrades, coordinates system implementations and approves the IT calendar. This group is co-chaired by the CC IT Enterprise Architect and a delegate of the Chief Technical Officer, meets weekly and includes representatives from the following teams: server, network, DBA, desktop support, interface, Citrix, testing, and developer groups.
- **The Functional Review Board (FRB):** The FRB reviews all functional changes to CRIS, including interfaces and ancillary systems. This group is chaired by the Deputy CIO, Clinical Informatics, meets weekly and includes representatives from the developer, testing, and executive groups.
- **Department Change Control Boards (CCB):** The various CCBs oversee the configuration management of specific department based systems. Members of the CCB consist of department stakeholders and IT systems administrators. A CC department designates the members and chair for these boards, the frequency with which they convene, and the issues they cover.

TAP Policies and Processes

The TAP specifies the following policies and processes:

- 1) Evaluation of new requests – The demand for new systems and technologies requires a review process that is responsive to the user and well defined for ease of understanding. The process begins with the submission of an IT Request on paper or electronically. The Chief of the Portfolio Office facilitates a review to ensure the request is complete and includes an assessment of the IT impact and work effort.
- 2) Each request is also reviewed within the IT department. Committee review team members include the Chief Portfolio Officer, Chief Technical Officer, Chief Enterprise Architect, and Deputy CIO, Clinical Informatics. The committee shall forward any requests requiring APB and security review to the appropriate committee. Projects requiring ITAG approval, based on defined criteria by the committee, are forwarded for further review and approval.
- 3) Evaluation of new technologies – Improved and changing technologies are occurring at a rapid rate for both health care and infrastructure systems. It is necessary to evaluate these systems quickly and systematically as early adopters are forcing changes into the infrastructure without much notice or review. To manage these events effectively, the APB shall:
 - a. Conduct business case reviews
 - b. Evaluate new technologies and document their finding through the use of Options Documents.
 - c. Conduct routine re-assessments of all current technologies

The APB shall present recommendations to management for decision and incorporation into IT budget and planning. The follow areas are scheduled for review in 2013:

- a. SunRay/thin client replacement
 - b. Database platform review (Sybase, Oracle, Microsoft)
 - c. Disaster Recovery at Sterling
- 4) Categorization of systems – Effective systems management requires the identification of each system with regards to it level of importance to the enterprise as a whole, its priority in relationship to user needs, budgeting priority, High Availability (HA), Disaster Recovery (DR) design, level of review required for security, and focus of system monitoring. Systems of a more critical nature will receive more resources than less critical systems. Each system shall be assigned one of the following categories:
 - a. Critical
 - b. Patient Care
 - c. Administrative
 - d. Hosted
 - e. Other
 - 5) Assessment of systems –Periodic system assessment with regards to function, priority, security, and role ensures that current IT systems continue to meet their mission. Each system will undergo assessment at the following times:
 - a. Annually via the HHS Authorization to Operate (ATO) requirement
 - b. EPLC Annual Operational Assessment requirement
 - c. Weekly configuration control boards via a System Change Request (SCR)

- d. Upgrade assessment as a member of the project team
 - e. Architectural changes via the Architectural Planning Board
- 6) Documentation of Systems – Architectural systems documentation is vital to sound IT systems management as the number of integrated systems increases and enterprise complexity grows. IT system planners, administrator, stakeholders, and users require a clear understanding on how their systems are designed and the dependencies they contain. All documentation changes shall be approved the Architectural Planning Board. The initial documentation shall be implemented by the enterprise architecture virtual team consisting of systems administrators and subject matter experts. Subsequent updates will be the responsibility of the project teams. Documentation production and review shall occur with the following events:
- a. Initial System Installation
 - b. Future projects related to the system
 - c. New integration with other systems
- 7) User Experience Requirements – The end user experience is vital to accomplishing the CC mission. The end users expect fast, accurate, available, intuitive, and friendly IT systems. To provide less than these requirements wastes the users time, delays data availability and potentially effects patient care. To meet these requirements, IT systems shall allow end users to access approved resources (applications, systems and data)
- a. On devices that work within their business process
 - b. In a format that allows them to understand the information
 - c. Access to workstations should take no longer than 15 seconds.
 - d. Access to Citrix should take no longer than 15 seconds.
 - e. Access to Critical Systems should take no longer than 15 seconds
 - f. From appropriate locations
 - g. 24/7/365
- 8) Monitoring of Systems – The monitoring of systems is important to both successful system management but also to maintain high availability and end user experience. The principle of identifying small problems before they escalate to larger problems is proactive systems management and excellent customer service. The APB shall designate systems for monitoring and review the downtime reports. Systems shall be monitored for:
- a. Availability
 - b. Performance
 - c. Memory usage
 - d. Storage usage

TAP Documentation

The TAP requires documentation of the operational environment in the form of System Architecture Descriptions (SAD), System Change Requests (SCR), Configuration Management (CM) documents, Service Level Agreements (SLA), service tickets, and Requirement Documents (RD). Together these documents foster a well-managed environment. See Appendix G: DCRI EA TAP for a complete review of the Technical Architecture Plan.

- 1) The System Architecture Descriptions SADs contains stakeholder views for each integrated system and sub-system. They show the interconnection between machines, the communication methods, and data exchanged, collected and managed. These are used by system administrators for troubling-

shooting, project managers to communicate system changes and enhancements, and managers for reporting on IT resources and budget justifications. The APB updates SADs as part their review process, the EA-VT as part of the initial documentation project.. Every system shall have a SAD.

- 2) The SCRs contain technical descriptions of proposed system changes. These are used by system administrators to document their work, coordinate between teams, allow for higher level technical review, and provide for management approval. Project managers use SCRs to task IT teams, track progress and coordinate project implementations. The documentation is produced or updated daily by staff and reviewed weekly by the TRB.
- 3) The REQs are technical requests for proposed new projects or initiatives. Every CC IT request is formalized by entering a REQ into the web-based CM tracking system. This system is used by customers to initiate an IT requests, management to evaluate, prioritize, classify and track each request, project managers to review initial high level requirements, and IT staff to suggest process improvements. REQs are entered or updated by the various user groups. Once approved, the information from the REQ is carried over into the scope of the project or initiative, or into a SCR, depending on the size and complexity of the request.
- 4) The CM plan contains each systems baseline and current configurations, the configuration items to track, ignore, or freeze, the approval needed for each type of change, and the work process required for each change. The CM staff references the CM plan to administer the SCRs.
- 5) RDs contain design and implementation descriptions for custom application systems. RDs are also used to document business rules for COTS systems. Various stakeholders use the RD to request and explain system changes, programmers use it to develop the code necessary to implement the proposed change, testers use it to verify the proposed changes works and meet the requirements. The project team's subject matter expert and system analyst create these according to the needs of the project.
- 6) Service tickets contain the information necessary for effective management of an IT service desk. Customers use the system to request service, IT technicians and managers use it to understand problems, communicate with the customer, and track progress. Service tickets are track primarily break-fix-install issues.
- 7) The SCRs contain technical descriptions of proposed system changes. These are used by system administrators to document their work, coordinate between teams, allow for higher level technical review, and provide for management approval. Project managers use SCRs to task IT teams, track progress and coordinate project implementations. The documentation is produced or updated daily by staff and reviewed weekly by the TRB.

NIH CLINICAL DATA CENTER

The NIH Clinical Data Center (CDC) currently houses over 700 networked devices providing both the Clinical Center and other NIH Institute users' access to data and applications. Management and administration of the information technology systems in the CDC (excluding application administration) is provided by a staff of 17 employees providing 24X7 coverage and support.

The CDC was designed to minimize potential risk and maximize potential growth for the next 10 years. This design encompasses at least N+1 redundancy for the three major systems required for CDC operation (power, cooling and network). The design also focused on minimizing physical risk due to environmental issues, such as water intrusion due to aging building infrastructure and failures. It is projected that we should be able to double the system's capacity of the current datacenter with the advent of new technologies such as server virtualization, blade technology, Storage Attached Network (SAN) devices and Network Attached Storage (NAS) devices that utilize physical space efficiently.

The CRC-B25756 Datacenter is shown in Table 5-2.

Table 5-2. Data Center Specifications

	CRC B25756
Number of devices in use	~700
Number of racks in use	112
Max number of devices	~900
Max number of racks	~95
Current power per device	314W (initial)
Current power per rack	2.1kW (initial)
Cooling capacity	35% (initial)
Power used	157kW(initial)
Max power available	360kW
Max power per rack	3.75kW
Percent power utilized	43% (initial)
Redundancy* of power/cooling	n+2
Limiting factor for growth	phys space
Largest single risk	TBD

As part of the Federal Data Center Consolidation the NIH CC participated in an NIH Test Audit of the Datacenter in 2011.

HHS defines an Agency Data Center as a data center is a repository (room or building) for the storage, management, and dissemination of data and information. This repository houses computer systems and associated components, such as telecommunications and storage systems. It generally includes redundant or backup power supplies, redundant data communications connections, environmental controls (air conditioning, fire suppression, etc.), and special security devices housed in leased, owned, collocated, or standalone facilities. The HHS Tier Classifications are listed below.

Data Center Tier Classification:

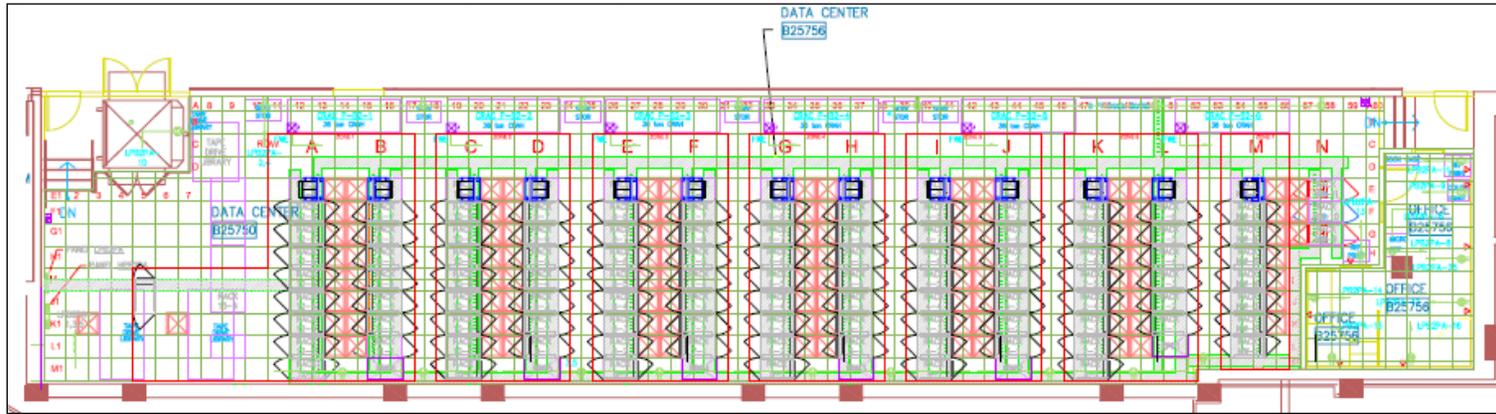
- Tier I: composed of a single path for power and cooling distribution, without redundant

components, providing 99.671% availability.

- Tier II: composed of a single path for power and cooling distribution, with redundant components, providing 99.741% availability
- Tier III: composed of multiple active power and cooling distribution paths, but only one path active, has redundant components, and is concurrently maintainable, providing 99.982% availability
- Tier IV: composed of multiple active power and cooling distribution paths, has redundant components, and is fault tolerant, providing 99.995% availability.

We meet Tier 3 classification as part of NIH Test Audit of the Datacenter in 2011.

Figure 5-1. NIH Clinical Data Center (CRC-25756)



DATA DICTIONARY

Data definition at the NIH Clinical Center is primarily a function of the Clinical Research Information System (CRIS), with all common data items sharing the definition as specified in the CRIS. The extensive interfacing of systems in either electronic or hard copy form assures continuity of these definitions throughout the NIH Clinical Center. The commonality of data definition allows aggregation and use in support of various administrative, quality improvement, research and patient care activities. The listing of specific data items is listed below.

The Entity/Application Matrix identifies the major applications that read or update key data entities. The Entity/Application Matrix is a useful analytical tool for understanding the significance of the various applications with respect to the information that they create or use.

Table 5-3. CRIS Data Entities by System

Applications	Entities																	
	Protocol	Patient Care Unit/Terminal	Resources	Authorized Prescriber	Staff	Patient	Patient Visit/Encounter	Lab Test	Radiology Exam	Procedure	Observations Assessments Charting Vital Signs	Lab Result	Radiology Results	Ancillary Results	Supply Item	Medication	Blood Product	
SCC SoftPath	X	X		X	X	X	X			X				X				
SCC SoftBank		X		X	X	X	X	X				X					X	
Clinical Data Repository	X	X		X	X	X		X	X	X	X	X	X	X				
Consult System (Tracking)	X	X		X	X	X												
ECG (OrderLink and Trace)		X		X	X	X	X			X				X				
CDW SYBASE	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
HSS (Hospital Statistics System)	X	X	X			X		X	X	X		X	X	X		X	X	
Lawson Materials Management					X										X			
SCC SoftMicro		X		X	X	X	X	X				X						
3M Softmed ChartFact		X		X	X	X												
Nutrition DFM System		X		X	X	X					X							
ORS (Occurrence Reporting System)	X	X		X	X	X	X											
CCM Opus (Respiratory Care System)				X		X												
PYXIS	X			X	X	X		X	X	X								
RIS (Radiology Information System)	X	X		X	X	X	X		X				X					

Applications	Entities																
	Protocol	Patient Care Unit/ Terminal	Resources	Authorized Prescriber	Staff	Patient	Patient Visit/ Encounter	Lab Test	Radiology Exam	Procedure	Observations Assessments Charting Vital Signs	Lab Result	Radiology Results	Ancillary Results	Supply Item	Medication	Blood Product
Surgery Information System (
3M Softmed Transcription System (and Electronic Signature Authority System includes reporting departments such as Rehab, EEG, EMG, and all Transcribed Reports.)	X	X		X	X	X								X			

INFORMATION CONFIDENTIALITY AND SECURITY

The collection, maintenance and use of patient information in medical records or other data storage systems at the NIH Clinical Center is governed by the Privacy Act of 1974, The Freedom of Information Act and the Public Health Service Act.

The NIH Security website <http://cit.nih.gov/security.html> contains all the policies, standards, guidelines for IT security at the NIH and has links to HHS IM and security documents.

Included in the activities that the Clinical Center undertakes to ensure confidentiality of patient data are:

1. Confidentiality training is part of the Clinical Center employee orientation process.
2. Access to the CRIS requires that users sign a statement affirming their responsibility for maintaining the confidentiality of their personal access code.
3. Access to any information systems containing confidential data at the NIH Clinical Center is limited to authorized personnel with specific authorized uses defined for each system.
4. The CRIS provides security through the use of authenticated sign-on for all authorized users. CRIS passwords are required to be changed every 60 days. Additionally, role-based access levels, transaction audit trails, terminal access time-outs based on a defined period of inactivity, system redundancy and storage of data off-site all work together to provide a robust security model aimed at protecting patient confidentiality and safety.
5. Network and email account passwords are required to be changed every 60 days, in compliance with HHS and NIH computer security policy.
6. The Clinical Data Repository protects data confidentiality with the same security model as the CRIS.
7. Computer security training is available via a Center for Information Technology website (<http://irtsectraining.nih.gov/>), and is required training for all NIH Clinical Center employees, fellows, volunteers and contractors who use computers.
8. All non-NIH organizations which have established dedicated Internet connections with the NIH must sign and actively support the requirements of an "NIH Network Interconnection Security Agreement".
9. The NIH Clinical Center maintains a confidentiality Education website designed to maintain staff's awareness of patient confidentiality and to address frequently asked questions about patient confidentiality. Questions regarding confidentiality may also be directed to the NIH Clinical Center Privacy Act Coordinator.
10. Remote access to CRIS from outside the NIH Clinical Center transmits information in an encrypted form.
11. The CASPER terminal services system provides authenticated / authorized users with remote, secure, encrypted access to administrative and clinical applications used throughout the NIH Clinical Center
12. There are systems in place throughout the Nursing Units, Clinics, and Clinical Center Departments to facilitate the proper maintenance, removal, and subsequent destruction of confidential hard-copy information. These systems are administered by the Housekeeping Department in cooperation with the Medical Record, Nursing and Patient Care Services Departments.
13. The Deputy Director for Clinical Care or Chief Information Officer is responsible for disciplinary actions, depending on the type and degree of infraction.
14. Security audits are performed to maintain system integrity.
15. Under the applicable laws and implementing regulations, employees of the NIH and the Department of Health and Human Services may have access to any information necessary to perform their assigned duties. In addition there are certain statutory exceptions and published routine uses of personally-identified information that do not require prior approval for release to individuals or organizations that are not part of the NIH. In brief, they are:
 - Physician(s) or organization(s) identified by the patient shall receive ongoing medical updates.

- The Social Work Department may share information to assist patients in the community.
- The Travel Office may inform public carriers of patient's special requirements, such as wheelchairs.
- Information regarding diagnostic problems or conditions having unusual scientific value may be shared with consultants.
- Information may be shared during audits of the operation of the NIH Clinical Center conducted by an outside federal agency.
- Congress may request information for matters within their jurisdiction or on behalf of constituent patients.
- Certain diseases or conditions, including infectious diseases, may be reported to appropriate representatives of State and Federal Government as required by law.
- Information may be released for statistical analysis without personal identifiers.
- Contractors may require access to certain information in order to provide a service. In such cases, all contractor personnel shall be subject to the requirements of the Privacy Act.
- Information may be released to facilitate the defense of a federal employee involved in a lawsuit.
- The Bureau of the Census or the National Archives may request records for survey, census or historical preservation.
- Information may be released in response to a court order or when the request comes from the head of law enforcement.

DCRI DISASTER RECOVERY/CONTINGENCY PLAN

The DCRI Disaster Recovery/Contingency Plan documents the NIH Clinical Center recovery of limited NIH Clinical Center Data Center operations after a disaster. The plan describes the preparation and actions required to effectively respond to a disaster, assigned responsibilities, and describe the procedures for testing and maintaining the plan.

The DCRI Disaster Recovery/Contingency Plan is available through the Chief Information Officer and Chief, Department of Clinical Research Informatics.

The following systems have failover capabilities to Building 12:

- CRIS Sunrise
- CRIS Interfaces
- CRIS CITRIX
- 3M
- SoftLAB
- RIS
- PACS

MONITORING

End-user experience monitoring, clinical systems performance monitoring and general hardware system monitoring comprises the key components to the Clinical Center’s (CC) monitoring program. The CC’s goal for end-user monitoring is to alert system administrators and management of IT problems experienced by the user at the time of occurrence and thereby shortens the resolution process.

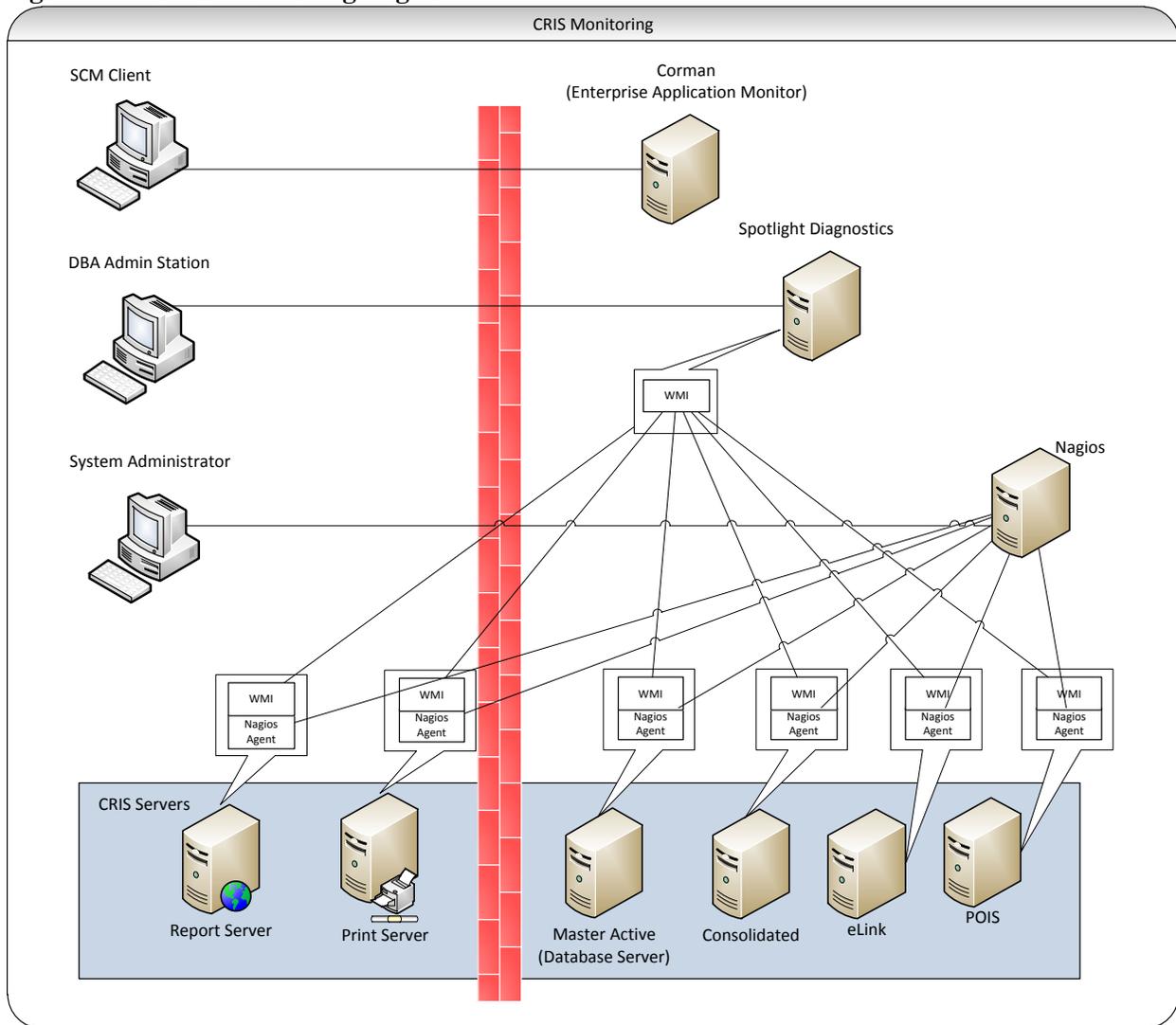
Clinical systems performance monitoring is focused on application performance as reported by software components. This information is displayed in color coded, highly graphical, data flow displays allowing System Admins (SAs) to observe and diagnose problems in real-time. This monitor is currently focused on clinical systems and will expand to other area over the next 12 months.

General hardware system monitoring focuses on traditional machine, network and disk IO and performance issues. Alerts and messages are sent based on CC set workload averages. The CC develops trend line analysis from this data for QA/QC.

Table 5-4. System Monitoring Goals

Goal	Result
Provide End User experience monitoring for CRIS	Installed and configured the Corman Enterprise Application Monitor. Configured monitoring alerts and QA/QC reports of end user experience
Provide database server monitoring for CRIS	Installed Spotlight Diagnostic server. Enables pro-active monitoring by CRIS DBAs. Establishes baselines database workloads and disk usage. GUI allows visual monitoring and trouble-shooting drill down.
Provide HW monitoring for server and VMs	Installed Nagios monitoring server. Enables pro-active HW monitoring by server team for all servers. Configured monitoring alerts. Establishes baselines cpu workloads and disk usage. GUI allows visual monitoring and trouble-shooting drill down.
Establish a Monitoring Program to govern the monitoring design and implementation	Established Monitoring Committee structure and workflow system for Monitoring Requests.
Procure a monitors of monitors (MOM) system for consolidated real-time monitoring	Conducted market survey of existing MOMs. Developed MOM requirements document. Proceeding to evaluation phase.
Provide End User experience monitoring for Ancillary systems	Installed Spotlight Diagnostic server for Oracle. Expanded to ancillary surgery system

Figure 5-2. CRIS Monitoring Logical View



Initial CC monitoring implementation is focused on improving clinical system’s performance and user experience. The CC monitoring plan calls for comprehensive monitoring of CRIS and all major Ancillary systems and applications. To accomplish this objective the CC is investing in monitoring tools and devices that deliver an enterprise wide solution.

MANAGING TECHNOLOGY

As part of managing the complexity of the environment it is necessary to develop and maintain a roadmap of all the technologies that comprise the existing Technical Infrastructure. Table 9-5 reviews the technologies within the current environment and the status of each technology. Annually as well as part of each project review we evaluate the addition of every new technology as well as the disposition any changes to a technology.

Table 5-5. Technology Roadmap

Technology	Version	2013	2014	2015
Wireless (WOWs)	802.11 G (VPN)	Retired	Replaced	0
Wireless (WOWs)	802.11 N (No VPN)	Deploy	In Use	In Use
Server OS	Mac 10x	12	12	12
Server OS	Win 2000, 2000S, 2000E	Retire	0	0
Server OS	Win 2003 S/E/E64	Retire 2003S 168	Retire 2003E 75	Retire 2003E64 -13
Server OS	Win 2008 S/E	45/40	10/40	Retire
Server OS	Win 2008R2 E	115	20	Retire
Server OS	Win 2008R2 S	210	200	100
Server OS	Unix - Solaris 10	20	Retire	0
Server OS	Unix - Solaris 11	25	45	Retire
Server OS	Unix – Solaris 12	0	Review	45
Server OS	Unix - Aix 5.3	Retire	0	0
Server OS	Unix - Aix 6.1/7.1	5/3	5/3	5/3
SAN	Clarion cx3-80/40/480	Retire	0	0
SAN	Clarion cx4-120	2	2	2
SAN	Clarion vnx-5300/5500	2/2	2/3	2/2
SAN	EMC RecoverPoint	8	8	8
SAN	Brocade 48000/5100	4/4	4/4	4/4
File Server	Sapphire	Retire	Retire	0
File Server	NAS	In Use	In Use	In Use
CITRIX	XEN 4.0/4.5/6.0	Retire	0	0
CITRIX	XEN 6.5	64	64	64
Virtualization	HpC7000- Win 2008R2 E	200	275	350
Development	C Sharp/Objects Plus	CRIS Only	CRIS Only	CRIS Only
Development	Ruby on Rails	Review	Review	Review
Development	Power Builder	Containment (10 Apps)	Retired	Retired
Development	.Net	Development	Development	Development
Development	Lotus Notes	Containment (3 Apps)	Retired	Retired
Development	4D	No New Systems	No New Systems	No New Systems
Development	PERL	UNIX Web Only	UNIX Web Only	UNIX Web Only
Development	Sharepoint	Development	Development	Development
Version Control	Subversion	In Use	In Use	In Use
Version Control	Version Manager	In Use	Retire	Retire
Configuration Management	TeamTrack	In Use	In Use	In Use
Service Center	Phone Support-Aspect	Retired		
Service Center	Phone Support-Angel	In Use	In Use	In Use
Service Center	Remedy	Retired		
Service Center	ServiceNow	In Use	In Use	In Use
Remote Support	CA Remote	In Use	In Use	In Use
Remote Support	Bomgar	In Use	In Use	In Use
Remote Support	WebEx	In Use	In Use	In Use

Table 5-5 Continued. Technology Roadmap

Technology	Version	2013	2014	2015
Database Servers	Oracle	COTS/No Development	COTS/No Development	COTS/No Development
Database Servers	Sybase	No New Development	No New Development	No New Development
Database Servers	Sybase Mobile	CBord Only	CBord go to MS SQL	CBord go to MS SQL
Database Servers	FoxPro	Go to MS SQL	Go to MS SQL	Go to MS SQL
Database Servers	MS SQL	Development	Development	Development
Database Servers	mySQL	Requires Waiver	Requires Waiver	Requires Waiver
Database Servers	dbVista	Retired	Retire	Retire
Interface Engines	QDX	Development	Development	Development
Interface Engines	eLink	Devices Only	Devices Only	Devices Only
Interface Engines	SCM/ISS	Development	Development	Development
Workstation OS	Windows XP	100	Retire	0
Workstation OS	Vista	Retire	0	0
Workstation OS	Windows 7	2700	2800	2800
Workstation OS	Mac OS Snow Leopard/Lion	In Use	Retired	Retired
Workstation OS	Mac OS Mountain Lion	In Use	In Use	In Use
MS Office	2003/2007 Mac 2008	Retired	Retired	Retired
MS Office	2010	In Use	In Use	In Use
MS Office	Mac 2008	Retire	Retired	Retired
Monitoring Tools	Corman EAM - SCM	In Use	In Use	In Use
Monitoring Tools	Clover Leaf Monitor - Interfaces	In Use	In Use	In Use
Monitoring Tools	Solarwinds - Network	In Use	In Use	In Use
Monitoring Tools	Nagios - Systems	In Use	In Use	In Use
Monitoring Tools	Up/Down Gold	In Use	In Use	In Use
Firewall/IDS/DMZ	Nessus	In Use	In Use	In Use
Firewall/IDS/DMZ	Cisco	In Use	In Use	In Use
Patch Management	Windows SUSS	In Use	In Use	In Use

CITRIX SERVICES

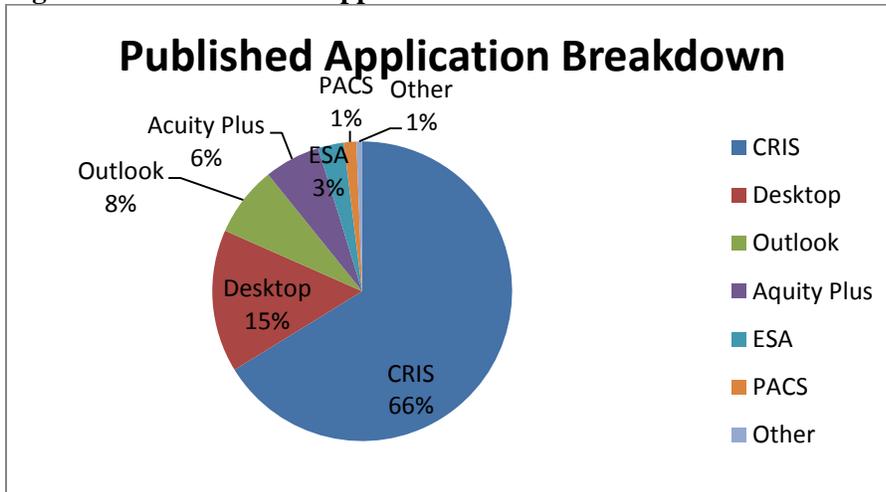
Citrix is the Clinical Center’s (CC’s) desktop virtualization technology for delivering clinical applications and systems to both workstations and mobile devices. Since 2002, the Citrix servers, through XenDesktop and XenApp, deliver software as a service to over 6,000 CC intramural program customers.

Table 5-6. CITRIX Goals

Goal	Result
Deliver individual applications to local and remote users	Web portal simplifies user access point to one web site
Bring new applications online quickly	Provision of an image to multiple servers minimizes image builds
Centralize storage	Users have access to their individual and departmental share drives
Provide complete availability in the event of a server failure	Built-in high availability and fault tolerance via Netscaler appliance
Disaster recovery (DR) for 100% application coverage	replication to building 12 is active
Deploy a highly scalable and agile IT infrastructure	Computing and storage capacity is easily added as needed, with no technology rework
Efficiently support a remote work-force	Virtualized desktops are device and location independent, enabling employees to work anywhere

Current Citrix published applications include CRIS, CC Desktop, Outlook, Acuity Plus and PACS. The Citrix servers provide one of two primary access methods to the hospital information system. A usage and operational breakdown are shown below:

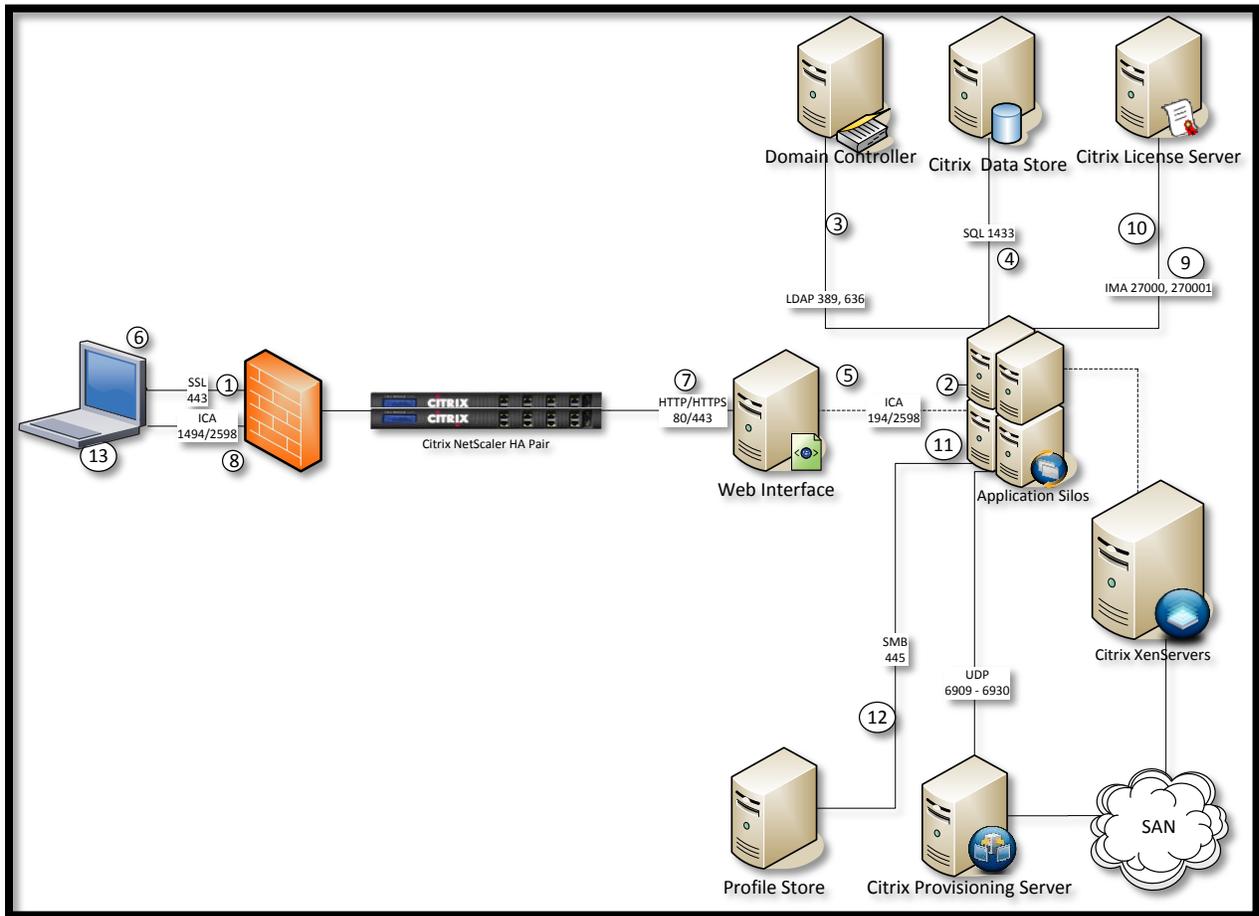
Figure 5-3. CC CITRIX Application Breakdown



2013 CITRIX Operational Statistics

- 4 Enterprise Applications servicing the NIH community
- 2 Enterprise Hosted Desktops
- 24/7 365 day access
- Smartcard authentication supported for remote and internal access
- Capacity of 250 Virtual CITRIX servers
- Standardization on HP Blades – 64 Physical Blades
- Introducing software pieces for orchestration using PVS
- Client support includes Windows, Mac, and UNIX.
- 4.5 Employees support the environment

Figure 5-4. CC CITRIX Architecture



For 2013 and 2014, the CC assigns Citrix the role of primary desktop virtualization technology with the goal of expanding applications and services to additional users and mobile devices.

NETWORK

NIHnet is the NIH Center for Information Technology’s (CIT) high-speed, highly available network providing IT infrastructure and services to all Clinical Center (CC) electronic resources - workstations, servers, wireless devices, radiology equipment, lab test equipment, and hosts. The NIHnet interconnects the CC LAN with the LANs of the other 26 NIH ICs located on the 310 acre Bethesda campus, NIH off-campus facilities in the DC metro area, other nationally located HHS Operating Divisions and other government agencies.

The CC’s operational responsibility involves managing all NIHnet related services and resources located in the hospital complex. These include the datacenter, radiology, laboratory, pharmacy, surgery, administrative areas, and clinics. The patient areas in the CRC are a shared responsibility with the CIT.

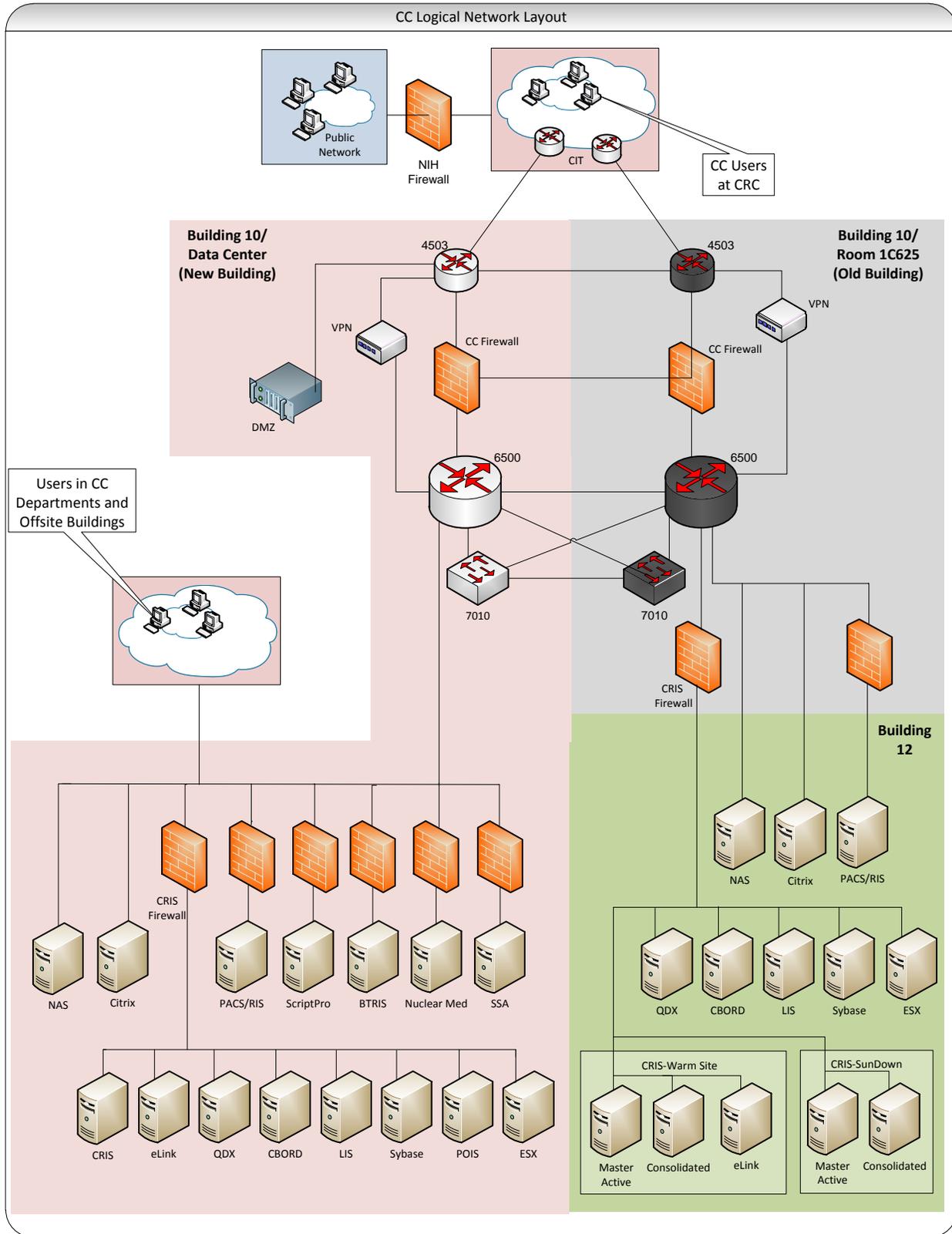
The CC’s network design plan is designed to achieve the following goals:

Table 5-7. Network Goals

Goal	Result
Provide Hi-Speed bandwidth to Servers and Patient Care systems	Upgrading “Last-mile” LAN connections to 1G for clinical equipment and servers. Workstations will upgrade according to the network equipment replacement schedule
Provide reliable Wireless capabilities to all hospital area	Implemented the wireless 802.11-n standard hospital wide. Continue to support a, b and g standards.
Provide wireless capabilities to hospital patients, guests and families	Created the Guest Wireless network as an open network that’s available hospital wide.
Support complete application availability in the event of a server failure	Dual-core LAN design provides Hi-Availability in the event of a server or network equipment failure
Disaster recovery (DR) for 100% application coverage	Network design provides identical subnet presence in multiple datacenters. Reduces DR complexity.
Deploy a highly scalable and agile IT infrastructure with Security-in-Depth.	Multi-tier firewall design provides 3+ layers of security depth for all clinical systems. Site-to-Site VPNs provide vendor service access in a managed access method. DMZ Design is in progress.
Efficiently support a remote work-force	The Netscaler and CC VPN appliances provide full coverage remote access and management.

The CC recognizes that current government initiatives in cloud computing bring the potential for network cost savings, greater reliability, and stronger disaster recover. The CC will incorporate these benefits in future network design initiatives.

Figure 5-5. CC Network Diagram



CC VIRTUALIZATION

Virtualization of x86 servers is the foundation for the CC's infrastructure modernization plan. Virtualization improves resource utilization, reduces costs, improves energy efficiency, improves the speed of resource delivery and encapsulates workload images in a way that enables automation. The Clinical Center (CC) purchased VMware's ESX system to support this plan.

At its core, ESX software solves the CC's problem of an ever growing demand for more applications and servers by enabling several operating systems and applications to run on one physical server or "host." Each self-contained "virtual machine" is isolated from the others, and uses as much of the host's computing resources as it requires.

The CC virtualization plan is designed to achieve the following goals:

Table 5-8. Network Goals

Goal	Result
Reduce datacenter costs	Physical server count reduced 30% with corresponding \$ savings
Bring new applications online quickly	Easy launch of Virtual Machines (VMs) from preconfigured templates
Centralize storage	All VMs on iSCSI storage
Provide complete application availability in the event of a server failure	Built-in high availability and fault tolerance
Deploy a disk-to-disk backup solution	Implemented data recovery with NAS
Disaster recovery (DR) for 100% application coverage	Host-based VM replication
Deploy a highly scalable and agile IT infrastructure	Computing and storage capacity is easily added as needed, with no technology rework

At the CC, the ESX system's primary responsibility is the replacement of physical servers with VMs. The support of virtualized desktops and mobile devices is primarily assigned to the CITIX system.

The CC recognizes this creates two virtualization technology silos, each managed with its own administrative solutions, skills, cost and complexities. However, the CC believes the footprint for both systems is small and evolving along a path that allows adjustment and flexibility without requiring expensive investments that render change prohibitive.

SECTION 5

PROJECTS 2011-2013

CORNERSTONE PROJECTS

In 2006, we initiated the concept of Cornerstone projects. DCRI defines a cornerstone project as one that combines many resources across multiple departments and is oftentimes organizationally mission-driven with high impact over multiple years. Identifying a project as a cornerstone identifies the project as being a priority in respect to resources and implementation dates. All other projects are coordinated and scheduled with these projects as the baseline. A list of the Completed Cornerstone Projects is below.

Table 5-1. Cornerstone Projects By Year.

2011	2012	2013	2014
<ul style="list-style-type: none"> • <i>Electronic ICU CDV</i> • <i>Blood Admin Bar Code</i> • <i>Outpatient Pharmacy</i> • <i>CRIS/SCM 5.5 Upgrade</i> • <i>Update RIS Interfaces</i> • <i>HSPD 12 Two Factor Local Access</i> • <i>NIH AD Migration</i> • <i>Disaster Recovery/High Availability</i> 	<ul style="list-style-type: none"> • <i>CRIS/SCM 5.5 Upgrade</i> • <i>HSPD 12 Two Factor Local Access</i> • <i>Medication Bar Code</i> • <i>Enterprise Scheduling (ES)</i> • <i>Replacement of Sapphire CC File Server</i> • <i>System Monitoring Program (SMP)</i> 	<ul style="list-style-type: none"> • <i>Medication Bar Code</i> • <i>Enterprise Scheduling</i> • <i>Patient Portal, Phase 1/3</i> • <i>Insurance Billing Pilot</i> • <i>System Monitoring Program (SMP)</i> • <i>Architecture Simplification (AS)</i> • <i>Protocol Order Set Services Center</i> • <i>Desktop Support Service Model</i> • <i>Clinical Reliable Equipment Assessment and Corrective Action</i> • <i>Merging and Development of Nursing Assessment / Treatment of Care Documentation and Development of Nursing Plan of Care /Problem List Process</i> 	<ul style="list-style-type: none"> • <i>Medication Bar Code</i> • <i>Insurance Billing Pilot</i> • <i>Patient Portal Phase 3/3</i> • <i>Enterprise Scheduling</i> • <i>CRIS/SCM 6.0</i> • <i>Referring Physician Portal</i>

Completed projects are in italics.

COMPLETED CORNERSTONE PROJECTS 2011-2013

A review of the Completed Cornerstone Projects is below.

Electronic ICU CDV

Objective: To migrate the existing paper documentation and instrument interfaces to an electronic ICU module that all users would be able to view all data collected within the ICU via CRIS Sunrise. To accomplish this objective, the following tasks were within scope:

1. Configure SCM with critical care content documentation and reports.
2. Create an inbound interface from the Phillips Intellivue Hemodynamic Monitors to SCM.
3. Create an inbound interface from the Drager Evita Ventilators to SCM.
4. Create an inbound interface from the Siemens Servo Ventilators to SCM.
5. Create an inbound interface from the Edwards Lifesciences Cardiac Output to SCM.
6. Develop the interface according to the specifications documented by the project team.
7. Configure the eLink and DataCaptor servers to allow data transmission through the firewall.
8. Configure SCM with the Clinical Data Viewer (CDV) to allow review of all documentation and interfaced results.
9. Place the resulting interface and configuration under CRIS Configuration Management.

Blood Admin Bar Code

Objective: The BEAPOCT solution is intended to address hospital-wide processes for positive patient identification, specimen collection and blood administration. There are four phases to the BEAPOCT project. Phase 4 included all activities required to implement barcode for the administration of blood products. To accomplish this objective, the following tasks were within scope:

1. The interface of Transfusion Medicine orders from CRIS to CareFusion and then to SCC.
2. The ability to administer blood products within CareFusion.
3. The vital signs interface from CareFusion to CRIS Sunrise.

Outpatient Pharmacy

Objective: To automate the Outpatient Pharmacy's repetitive, manual dispensing tasks most subject to human error. To accomplish this objective, the following tasks were within scope:

1. Install the ScriptPro's (vendor) hardware and software in the NIH DCRI Data Center.
2. Reconfigure the Outpatient Pharmacy work area to allow installation of ScriptPro's robotic dispensing system and associated workstations and bar code readers.
3. Develop interface to send Outpatient Pharmacy patient information and medication orders from SCM to ScriptPro.
4. Develop interface to send dispensing information from ScriptPro to SCM according to approved requirements.
5. Develop a data feed for DTI costing information per approved requirements.

CRIS/SCM 5.5 Upgrade

Objective: Refresh the current hardware and software to support and take advantage of new technology for SCM Production and Development servers (e.g., increase memory, improved CPU and disk I/O performance and storage capacity and the new functionality within SCM 5.5). To accomplish this objective, the following tasks were within scope:

1. Upgrade SCM 5.0 to SCM 5.5, including Sunrise Acute Care, Sunrise Pharmacy, Eclipsys Gateway, Eclipsys Auditing Services, Eclipsys Security Services, the Clinical Data Viewer and the Sunrise Interface SubSystem.
2. Comply with the DHHS NIH enterprise Active Directory and technology model.
3. Build and provide the new SCM 5.5 Citrix Xenapp server farm that supports an improved user experience with the SCM 5.5 client.
4. Ensure continued interoperability with existing ancillary applications that share interfaces with SCM.
5. Ensure interoperability with current Standard Clinical Desktops (e.g., various SCD version, WOW's, Sunrays, etc.) and to add support for new client operating system such as Windows 7.
6. Update the training materials, user manuals and system documentation impacted by the upgrade.
7. Provide training on new and/or enhanced features included in the upgrade for Sunrise users.
8. Modify the SCM configuration required for the upgrade to SCM 5.5 (e.g., environmental profile settings, security settings, interfaces, etc) as needed.
9. Validate the entire upgrade process in a rehearsal environment prior to the go-live.
10. Design and provide improved operations and maintenance management of the SCM systems (e.g., define how to manage Microsoft Patches, SCM Patches, hot fixes and updates, backups, server maintenance, etc).

Update RIS Interfaces

Objective: The CERNER Radiology Information System was replaced with the CareStream Radiology Information system. To accomplish this objective, the following tasks were within scope:

1. Analyze existing ADT, orders and results interfaces against the new Carestream Radiology Information System interface requirements.
2. Identify and update or document changes needed to interfaces that connect to the legacy RIS (Cerner).
3. Update, create and implement new inbound and outbound interfaces based on analysis with as few changes or customizations as possible.
4. Provide the same degree of functionality in the new interfaces as with the current interfaces.
5. Analyze, document and implement infrastructure changes (e.g., SAN switch, IP network) to support new RIS architecture.
6. Create a Test Plan, test scripts and scenarios, test summaries and results.

HSPD 12 Two Factor Local Access

Objective: The HSPD 12 regulations required that all Windows Based Devices required two factor authentication. At the NIH CC this was done through utilizing the PIV Card as part of the authentication process. To accomplish this objective, the following tasks were within scope:

1. Update CITRIX to require two factor authentication for remote access.
2. Develop a process for users without PIV cards to access CRIS and CC Resources for an approved amount of time.
3. Deploy keyboards with card readers and USB card readers across the CC.
4. Install any necessary software to allow the use of the PIV Cards and to allow the use of the PIV Card to send and receive encrypted email.

NIH AD Migration

Objective: The decision to consolidate Child Domains at the NIH was required by the NIH CIO. To accomplish this objective, the following tasks were within scope:

1. Create a simplified resource architecture in the NIH domain that meets CC security, functional and technical requirements.
2. Establish architecture standards for creating, populating and maintaining AD objects in the new CC resource architecture in the NIH Domain.
3. Migrate all AD objects, resources and functionality (e.g., workstations, servers, users, printers, organizational units (OU), group policies (GPO), applications, web sites, etc.) to the new CC architecture in the NIH domain.
4. Provide like-for-like network/application functionality to user.
5. Minimize service interruption or disruption to users.
6. Retire the CC Domain and delete all remaining objects.
7. Eliminate the use of native Active Directory Tools within DCRI.

Disaster Recovery/High Availability

Objective: Establish High Availability/Disaster recovery/Failover services for the following Windows based applications SoftMed, ATV, EKG, CBORD, Esprit, Acuity Plus, and ANSOS and the UNIX based applications of IDMS and Sybase. To accomplish this objective, the following tasks were within scope:

1. Establish the Infrastructure necessary to support the Disaster Recovery of Mission Critical Applications
 - a. Install Core network services to support network functions independent of bldg 10 connectivity
 - b. Install switches to support server technology
 - c. Install domain services (domain controller, DHCP, etc)
2. Implement failover services using one of the following technologies:
 - a. VMware
 - b. Geographic Clustering
 - c. Online spare
 - d. Cold Spare
3. Establish an online storage system to enable quick backup and restore for mission critical systems.

Replacement of Sapphire CC File Server

Objective: The existing Sapphire File Server was at end-of-life as well as there has been multiple performance issues and downs affecting CC Users. A replacement was needed. To accomplish this objective, the following tasks were within scope:

1. To install redundant NAS servers in building 10 (primary) and building 12.
2. To develop and deploy an appropriate network infrastructure to handle the new NAS architecture.
3. To train CC DCRI staff (and end users, as appropriate) on how to manage data in the new system.
4. To migrate all existing Sapphire data to the NAS with minimal disruption.
5. To place the resulting interface and configuration under CRIS Configuration Management.

OPEN CORNERSTONE PROJECTS 2011-2013

A review of the Ongoing and Planned Cornerstone Projects is below.

Insurance Billing Pilot

Objective: The issue of charging for services delivered to patients at the CC has surfaced several times in its history, and is now moving from theory to application as the CC makes plan to implement an insurance billing pilot:

In 2010, the Congressional Appropriations Committee Report (CACR) included the following language: *“The Committee directs NIH to conduct a review and begin a three year pilot program by April 1, 2011 to determine the feasibility of a Insurance Billing Pilot program, and urges NIH to coordinate with other agencies such as the Department of Veterans Affairs in this effort. The Committee requests a report by December 1, 2010 that describes the review, pilot timeline, and criteria planned to evaluate the pilot, with future updates in preceding budget requests.”* As a result of this CACR, the CC contracted with PricewaterhouseCoopers (PwC) in 2011 to conduct a study that would examine the feasibility of Insurance Billing Pilot (currently referred to as “insurance billing” to clarify that the focus is on insurance, not patient, billing). As a result of the findings and presentation to the CC governing bodies, consensus was reached that the risks associated with the uncertain financial viability, coupled with the potential deleterious impact on the NIH clinical research mission, outweighed the potential benefits that might be realized.

Following the PwC report, and as part of its fiscal year 2012 appropriations conference language, Congress directed the NIH to conduct an insurance billing pilot: *“... The conferees ... direct NIH to conduct a 3-year pilot study to assess the viability of Insurance Billing Pilot at NIH by looking at one of the services commonly used by a significant number of outpatients at some point in the patient’s protocol. One possible example would be radiology services, but this is not the only option. The Committees on Appropriations expect to be briefed on the proposed subject area and scope of the pilot before it is finalized. The conferees include \$10,000,000 for the Clinical Center for the costs of building the billing infrastructure for the pilot.”*

In response, the CC initiated its pilot design phase, in collaboration with McKinsey & Company, to develop a pilot that best represented the complexities of implementation in a clinical research setting and provide a realistic evaluation of the potential opportunities and untoward outcomes. Based on the recommendation of the CC governing bodies, it was decided that the pilot will bill the payors of

commercially-insured patients for services in two outpatient areas, outpatient radiology and outpatient procedures. The Committees on Appropriations staff were briefed on this design and scope on March 28, 2013. Since then, the CC has engaged the partnership of PwC to help the CC put process and infrastructure in place for insurance billing, and integrate the activities of the billing vendor (selection pending), responsible for implementing the nuts and bolts of a billing system. The CC's ultimate goal is to send out its first bill by the end of January 2014.

As part of the Insurance Billing Pilot Program there are eleven projects that will require DCRI involvement:

1. Insurance Collection Configuration
2. NPI Updates via SACRED to CRIS Sunrise
3. Diagnosis/Med. Necessity/Problem Lists configuration within CRIS Sunrise
4. Order Interface for the procedure area items between CRIS, Provation and SoftMed
5. Segregation of Billable Items
6. Implementation of the Staging Database
7. Implementation of the Billing System including interfaces from the Staging Database to the Billing System
8. Interfaces with Billing System to NBS
9. Protocol Management including Protocol Order Set Development
10. SCM 6.X Implementation
11. ICD-10 Implementation
12. HIPAA Risk Assessment/Training/Process Development

Enterprise Scheduling (ES)

Objective: The Enterprise Scheduling project is a 3-phase implementation to support a standard scheduling model throughout the Clinical Center. The phases include (1) Deployment of an Electronic Appointment Request (EAR) system, (2) Implementation of the Allscripts Enterprise Scheduling system, and (3) deployment of a new Encounter Model for outpatient visits to the CC. To accomplish this objective, the following tasks are within scope:

1. Define and document the current scheduling workflows for impacted departments.
2. Define and document the future scheduling workflows for impacted departments.
3. Implement the Allscripts Enterprise Scheduling System in a phased approach according to the approved implementation plan.
4. Configure the Enterprise Scheduling interfaces according to approved requirements.
5. Define and develop a training plan and execute the plan to ensure all end users are trained prior to utilizing the system.
6. Configure the CRIS Sunrise for an Encounter Model process based on options selected and approved requirements.

Patient Portal

Objective: The goal of this project is to implement a secure, web-based Patient Portal to help provide communication services between patients and their NIH Care Teams. The NIH patient advisory group has been requesting access to their medical information. The CC-OD would like an option for granting this access electronically. Implementing the Sunrise Patient Portal allows for closer communication between

care providers and patients via Secure Health Messaging. It enables patients to view their medications, wellness schedule, immunization information, results and personal registration information in a secure way with controls over the information that the care provider team releases to the patient. It also supports survey and form completion (which is not part of the scope). This solution includes features that help healthcare organizations achieve ARRA Meaningful Use.

The implementation scope of each phase as far as what is included in the Patient Portal will be as follows:

Phase 1

- Key information about the NIH/Clinical Center, e.g. directions and clinical studies
- Selected Laboratory results
- Medical Record documents, e.g. First Registration report, Discharge summaries

Phase 2

- Selected Radiology results

Phase 3

- Email Communication between Patient and Provider

To accomplish this objective, the following tasks are within scope:

1. To configure and implement a web-based patient portal which provides read-only access to selected healthcare information from CRIS Sunrise.
2. To create the patient portal website and configure related firewalls for secure remote access.
3. To install and configure any required hardware and software components, including Secure Health Messaging (SHM).
4. To configure CRIS Sunrise results and document types for how read-only access will be granted to the patient, e.g. automatically, or clinician release.
5. To document, communicate and activate a process (CC policy/ procedure) for granting patient access to the portal and their approved medical information.
6. To create a new support area within the Medical Record Department for handling patient portal customer service inquiries.
7. To place the module under CRIS Configuration Management, and develop any necessary security and privacy documentation, and update relevant CRIS Configuration SOPs.

Medication Barcode

Objective: The Medication Barcode system shall provide the ability to support the medication administration process, including verification of the right patient, right drug, right dose, right strength, right time and right route of administration and clinical reason as appropriate. Bar Code Aided Medication Administration (BCMA) involves the commitment of prescriber, pharmacist, nurse and patient to a safer and more efficient process surrounding the medication function.

To accomplish this objective the following tasks are within scope:

1. To configure and implement KBMA within CRIS Sunrise.
2. To develop a web-based system to allow the scanning and association of medication and their barcode.
3. To develop a training environment, including training materials.
4. To update the environment to ensure that there are Clinical Reliable Equipment (see Clinical Reliable Equipment Assessment and Corrective Action).
5. Deploy across the enterprise in a phased approach.

Protocol Order Set Service Center

Objective: To enhance customer service by: Standardizing the submission process for protocol and departmental order set requests; ensuring departmental review of protocol and departmental order set

requests; and developing a process to standardize the analysis, development, and implementation of protocol and departmental order set. To accomplish this objective, the following tasks are within scope:

1. Define Protocol Order Set Service Center (Function/Purpose)
2. Define Service Center Team Members
3. Define roles and responsibilities of team
4. Request a contact(s), from each ancillary department, who would be responsible for reviewing requests for protocol/departmental order sets that impact their specific area.
5. Document a Protocol Lifecycle (from IRB approval through termination)?
6. Define process for handling new protocols, updates, termination and annual review of existing protocols
7. Create standards/style guides for order set forms
8. Create order set form templates
9. Convert all quick order sets to order set form
10. Convert one chemo order set to order set form
11. Provide end user training and support documentation for CRIS Support & Systems Monitoring

CRIS/SCM 6.X

Objective: Upgrade the database to MS SQL 2012 to allow database mirroring and to update the software to take advantage of new functionality within SCM 6.X including the ability to implement ICD 10. To accomplish this objective, the following tasks are within scope:

1. Upgrade SCM 5.5 to SCM 6.X, including Sunrise Acute Care, Sunrise Pharmacy, Eclipsys Gateway, Eclipsys Auditing Services, Eclipsys Security Services, the Clinical Data Viewer and the Sunrise Interface SubSystem
2. Comply with the DHHS NIH enterprise Active Directory and technology model.
3. Build and provide the new SCM 6.5 Citrix Xenapp server farm that supports an improved user experience with the SCM 6.X client.
4. Ensure continued interoperability with existing ancillary applications that share interfaces with SCM.
5. Ensure interoperability with current Standard Clinical Desktops (e.g., various SCD version, WOW's, Sunrays, etc.) and to add support for new client operating system such as Windows 7.
6. Update the training materials, user manuals and system documentation impacted by the upgrade.
7. Provide training on new and/or enhanced features included in the upgrade for Sunrise users
8. Modify the SCM configuration required for the upgrade to SCM 6.X (e.g., environmental profile settings, security settings, interfaces, etc) as needed.
9. Validate the entire upgrade process in a rehearsal environment prior to the go-live.

Referring Portal

Objective: CC-OD would like an option for granting referring clinicians access to patients records for which the patient has signed a consent authorizing the physician to review his/her record. The Referring Physician Portal will provide communication services between the referring physician(s) of patients and that patient's NIH Care Team. Referring Physicians will be able to log in to the provider system to view clinical information, orders and results and use Secure Health Messaging to communicate to the NIH Care Team. To accomplish this objective, the following tasks are within scope:

1. Implement the web based Allscript Clinician Portal that uses the same database as SCM.
2. Develop a testing plan for end users and implement.

3. Develop a training plan for end users and implement.
4. Document and communicate a process for granting chart access to only patients for which the clinician (in this case the referring physician) has a role.

COMPLETED PROJECTS 2011-2013

Table 5-2. Completed Projects 2011

Type	Title	Description
Administrative	CRIS Train Refresh	Refresh of the CRIS Training system
Administrative	IIS Web App Migration	Migrate a series of web servers to new hardware for load balancing and enhanced change control with dev/pre-prod environments
Administrative	Patient Library	Update the Patient Library, a web-based proprietary database with 5 client workstations and no PII
Administrative	RVS-Contact Mgmt	Develop and implement the contact management module for Patient Recruitment System.
Ancillary	3M Upgrade	Upgrade MRD 3M (SoftMed) applications to platform 7
Ancillary	Barcode Phase 3	Implement barcode for Inpatient lab specimen collection
Ancillary	Barcode Phase 4	Implement barcode for blood administration
Ancillary	CBORD Upgrade	Upgrade to the next version of CBORD Nutrition system
Ancillary	LIS Upgrade	Upgrade to SoftLabMic, SoftBank, SoftPath and interfaces
Ancillary	OPUS Upgrade	Upgrade the Respiratory Information System OPUS-RT application to the latest version: 5.1.105
Ancillary	RAD Results Viewer	Create an application to access results quickly for Radiologists from within the Radiology Information System
Ancillary	SCM: ICU	Add ICU documentation & device interfaces to SCM w/CC content
Ancillary	TheraDoc Ph 2	Implement Vital sign and Surgery interfaces
Ancillary	Update RIS Interfaces	DRD implemented a new RIS system (EPLC) which required updates to all current RIS interfaces
Ancillary/CRIS	HistoTrac Interface	Develop ADT, Order & Results interface between SCM and HistoTrac HLA system through the SCC LIS
Ancillary/CRIS	OP Pharmacy	Implement an OP Pharmacy system for Take Home medications
Ancillary/CRIS	ProVation	Upgrade ProVation which is used to manage bronchoscopies and endoscopies. This included the ADT interface w/SCM & Provation
CRIS Sunrise	Electronic Patient Consent	Added a module for patient to sign consents to be integrated with CRIS Sunrise
CRIS Sunrise	PDF in SCM	Implemented a repeatable process for bringing pdf files into SCM in 4 phases, with future additions to be completed by SCRs using the repeatable process. This included the ability to post PDFs as part of results, significant events, consents, protocol consents and advance directives.
CRIS Sunrise	SCM Cold Failover Environment	Created an environment to allow the creation of DR site in the event of failover based on log shipping of CRIS SCM files.
CRIS Sunrise	SCM Sunrise Read Only Site	Created an environment to the creation of an environment used when there are short downs to allow CRIS users to access all the information within CRIS in a read-only format.
Infrastructure	Blade Servers	Migrated Servers to Blade Servers
Infrastructure	CITRIX Upgrade	Upgrade to Presentation Server 4.0
Infrastructure	DR-HA	Implemented DR-HA for SoftMed, ATV, EKG, IDMS, RIS, CBORD, ProVation, eSprit, AcuityPlus, Ansos, Sybase and LIS
Infrastructure	Non-CC Hosting	Provided 4 Racks available to ICs for non-CC equipment
Infrastructure	Network Switch	Split Network Core Installation based on F Wing relocation
Infrastructure	NIH AD Migration	NIH AD Infrastructure change to consolidate CC child domain
Infrastructure	SAN Upgrade	Migrated 2 SANs
Infrastructure	Network Upgrade	Removed 15 networked devices, replaced 30 networked devices, installed 20 new networked devices

Table 5-3. Completed Projects 2012

Type	Title	Description
Administrative	ANSOS Web-Scheduler	Activated the Web-scheduler functionality within ANSOS and post related URL on SCD and CITRIX
Administrative	DPM AQI	QI database for DPM for tacking standards and metrics.
Administrative	Hand Hygiene Compliance	Add this quality indicator to the existing Clinical-Executive Dashboard for entry of hand hygiene compliance monitoring data from all hospital units, clinics and departments.
Administrative	3M Hand Hygiene	Provided support for the pilot of a system to track Hang Hygiene
Administrative	MRD Protocol Website	Implemented a solution to review active and removed protocols from an institute system, and auto-update accordingly in SCM
Administrative	NDSR Upgrade	Upgrade the current NDSR application and Sybase database
Administrative	ORS Update (Patient Falls)	Updated ORS to separate patient falls from other falls and match data entry with CRIS documentation
Administrative	TeamTrack - Mashups	Upgraded the Configuration Management tool Serena TeamTrack to the next phase, called Mashups
Administrative	Wristband printers for clinics	Deployed 25 wristband printers for DH, OR and OP clinics; Make changes to CRIS Orders, CRIS security, Standard Register and Standard Register printers.
Ancillary	CBORD Tray Monitor	Implemented a CBORD Nutrition module to display the status of all meal trays currently awaiting delivery
Ancillary	CBORD Upgrade to 9.10	Upgraded the existing Nutrition CBORD system from version 8.8 to version 9.10
Ancillary	Dictation System Upgrade	Upgraded existing dictation system, including all hardware and software
Ancillary	Endoportals Implementation	Implement Endoportals to allow swallowing videos to be available at any time on a single system
Ancillary	LIS & SoftWeb Upgrade	Add SoftWeb module to LIS which allow patient results to be available to remote locations via the Internet
Ancillary	TheraDoc Upgrade	Upgraded Theradoc Applications
Ancillary	Upgrade CareFusion SCV and TV	Upgraded current SCV and TV to GA versions 2.2.1 and 2.2 respectively.
Ancillary/CRIS	Mammogram Ordering Process	Created a new orderable and resulted process to allow mammograms to be done by an outside facility but ordered and resulted in CRIS
Ancillary/CRIS	Genetic Mutation - Athena	Created a new orderable for Athena Genetic Tests; Modify FileBOT to post inbound results to CRIS Sunrise, linked to the Genetic Test order
CRIS Sunrise	Contrast Orders within RIS	Created interface to document Contrast Orders within the workflow of RIS and send to SCM
CRIS Sunrise	Link SCM to RadLite Viewer	From the Radiology Results in CRIS users can access images via the RadLite PACS viewer
CRIS Sunrise	Outside Records in SCM	Utilized the current 'Bot' structure to display scanned documents in SCM
CRIS Sunrise	SCM Post-RU6 Hotfixes	Install critical Hotfix to address patient safety issue of documents grouping under incorrect disciplines
CRIS Sunrise	SCM 5.5 Upgrade	Upgrade SCM to version 5.5
CRIS Sunrise	SCM ICU Phase 2	Interfaces between the Gambro PrismaFlex devices and CRIS Sunrise for use in the ICU with changes made to the Clinical Data Viewer (CDV)
CRIS Sunrise	Upgrade Sign-Out Tab	Create a new, tile-based sign-out tab in CRIS Sunrise for ACGME
Infrastructure	BTRIS Firewall Upgrade	Replaced existing Cisco PIX firewalls with new Cisco ASA firewalls (primary and failover); Configure firewall based on current settings and

		test
Infrastructure	CC Website Upgrade/Migration	Migrated all websites (except Clinical Studies) off Monet and onto Shasta and McKinley
Infrastructure	CITRIX Netscaler Upgrade	Upgrade CITRIX Netscaler
Infrastructure	DR-HA	Implemented DR-HA for SoftMed, ATV, EKG, IDMS, RIS, CBORD, ProVation, eSprit, AcuityPlus, Ansoos, Sybase and LIS
Infrastructure	Google Mini for CC Website	Procure, configure, and implement a Google Mini Search Appliance for the inventory of assets database on the CC Website
Infrastructure	Non-CC Hosting	Provided 4 Racks available to ICs for non-CC equipment
Infrastructure	Mobile Iron	Installed mobile device management software and configure to support security policies
Infrastructure	Monitoring Program	Developed a program in which the monitoring for all the CC systems is analyzed, reviewed and approved
Infrastructure	NAS (Sapphire Replacement)	Installed new NAS equipment in the CC Datacenter and Bldg. 12, and transition existing Sapphire data and users to the new hardware
Infrastructure	Network Upgrade	Removed 20 networked devices, replaced 35 networked devices, installed 65 new networked devices
Infrastructure	NIH AD Migration	NIH AD Infrastructure change - Child domain consolidation
Infrastructure	HSPD-12 PIV Access Via CRITRIX	Configured CITRIX to allow access to CTIRIX via PIV
Infrastructure	HSPD-12 PIV	Roll-out of PIV Card Readers to all Users
Infrastructure	QDX Upgrade	Update QDX from version 5.6 to version 5.8
Infrastructure	Sybase Upgrade	Upgrade all Sybase Servers to current version of Sybase
Infrastructure	UNIX Server Upgrades	Migrate UNIX Servers to new servers
Security	Web Security	Develop web security gateway

Table 5-4. Completed Projects 2013

Type	Title	Description
Administrative	AssetTracker	Installed system to track all WOWs, PDAS, Label Printers and all Data Center Equipment
Administrative	Credentialing Evaluation System	Created a process to present the correct survey (FPPE vs. OPPE) to supervisors of physicians as part of the credentialing life cycle.
Administrative	IDMS Upgrade	Upgraded IDMS application to release v36; Pharmacy to work directly with vendor for upgrade
Administrative	Implement Quick Test Pro	Implemented Quick Test Pro to provide efficiencies for regression testing, release testing, performance testing and web app testing
Administrative	Pharmacy Wait-time Rewrite	Developed Pharmacy Wait-time web application based on requirements from existing Power Builder application
Administrative	Phlebotomy Wait-time Rewrite	Developed Phlebotomy Wait-time web application based on requirements from existing Power Builder application
Administrative	RMD-CMS Analysis	Configured a server to download a one-time flat file from CMS for Rehabilitation Medicine Project
Administrative	Service Center Model	Moved to a Service Center Model to provide technical desktop support
Administrative	SOFiE Implementation	Purchase, install and configure SOFiE for use by OFRM and OAM for budget management
Administrative	Web Application Server	Create a web Application server for various stages of DCRI development efforts– from prototyping all the way to production-level environments

Ancillary	PPC Documents (eSphere)	Migrated all Pain and Palliative Care clinical documentation into CRIS, added reports and clinical summary views to replace Eprit Esphere
Ancillary	Replace I-Stat Analyzer (PrecisionWeb)	Installed new web application - XceedPro; Update Telcor to provide Blood Gas Data Manage in ICU
Ancillary	RIS DR Failover Test	Tested RIS operation in DR Failover mode
Ancillary	RT Ventilator Replacement	Procured and installed 6 new Dräger Evita Infinity V500 devices to replace all existing ventilators used by RT
Ancillary	StemLab Upgrade	Upgraded StemLab to Version 3.6.2
Ancillary	Surgical Information System Upgrade	Upgraded Surgical Information System Hardware, Application and clients
Ancillary	Upgrade RIS database	Upgraded RIS Oracle database and implement DR/HA system (no changes to client)
CRIS	Cardiac Energetics Reports	Interface Cardiac Energetics Reports in SCM from LCE System
CRIS	Chemotherapy Order Set Redesign	Redesign Chemotherapy Protocol Order Sets to have a more usable design.
CRIS	Patient Portal Phase I	Implemented phase I of the Patient Portal
CRIS	Pharmacogenomics	Implemented Pharamocogenomics for HLa testing with three medications
CRIS Sunrise	NCI-Labmatrix Interface	Created interface from NCI's Labmatrix system to SCM for the Research Tissue Procurement Request
Infrastructure	4D	Migrated all 4D Databases to current version on Windows
Infrastructure	Backup	1. Migrated from BackUp Exec to NetBackup 2. Migrated from old to new backup hardware
Infrastructure	CITRIX	1. Implemented 6.5 environment 2. Migrated all applications to 6.5 environment 3. Retired 4.0, 4.5 and 6.0 CITRIX environments
Infrastructure	DHCP	Migrated DHCP Servers to new hardware
Infrastructure	ePolicy	Implemented central administration of antivirus and security settings
Infrastructure	ESX	Upgraded ESX Virtual Server Environment
Infrastructure	Monitor Tool Implementation	Implement monitoring tools for SCM 5.5 and NAS
Infrastructure	Monitoring	Implement monitoring tools and processes to manage the systems and their logs. This includes Corman for SCM
Infrastructure	Network Upgrade	Removed 50 networked devices, replaced 20 networked devices, installed 150 new networked devices
Infrastructure	Non-CC Hosting	Provided 6 Racks available to ICs for non-CC equipment
Infrastructure	SANs	Migrated 2 SANs, Retired 3 SANs
Infrastructure	Sybase DBCC Environment	Created separate environment to process DBCC for Sybase databases
Infrastructure	Wireless 802.11n	Migrated the CC to 802.11n and remove the requirement for VPN
Infrastructure	WOW Replacement	Replace all computers within WOWs with 64 Bit Win 7 computers
Security	ArcSight	Installed ArcSight on servers to forward CC logs files to NIH
Security	CC DMZ	DMS with IDS implemented and configured
Security	MIR	Implemented Mandiant Intelligent Response (MIR) agent on all Windows workstations and servers (excluding virtual)
Security	Nessus Scans	Installed and configured server to allow Nessus Teneable Scans
Security	NIH DLP	Participated in NIH DLP (Data Loss Protection) feasibility study conducted with CIT

Table 5-5. Expected to be Completed 2013

Type	Title	Description
Administrative	ATV Redesign	Implement enhancements as identified by Admissions/ATV Redesign Group
Administrative	Protocol Order Set Service Center	Define POSSC workflow process of order sets across ancillary departments
Ancillary	Omnicell Upgrade	Upgrade Omnicell to v14 (FoxPro to SQL) and add new cabinets
Ancillary	ProVation MD Upgrade	Upgrade ProVation to the latest version; Replace all hardware; Migrate to Unix servers
Ancillary	Radiance Software Install	Install Radiance software and build an interface with SCC
Ancillary	Scheduling Upgrade (v.35)	To upgrade the existing Scheduling.com application and database to v. 35
CRIS	ABO Minor Incompatibility	Establish a process for identifying patients with an ABO minor incompatibility after transplant.
CRIS	Change Barcode Generation	Remove dependence and complexity on legacy IDAutomation Barcode Font, and improve readability for IDMS and KBMA
CRIS	SCM Research Blood Serial	Give prescribers the ability to place a serial Research Draw order in SCM, and provide information in SCM around the collection dates/times of each tube drawn in the serial draws.
Infrastructure	Clinical Center DMZ	Develop a Clinical Center DMZ for location of public facing webservers, external IP addresses, VPN servers, Citrix Netscaler servers, and Webapp servers.
Infrastructure	IDS Project	Purchase and implement and network Intrusion Detection system (IDS) in the CC DMZ
Infrastructure	SAN-Sybase/MS SQL Migration	Replace the existing Storage Area Network (SAN) and migrate all existing applications
Infrastructure	SCD Replacement	Replace all Standard Clinical Desktop Computers across CC
Infrastructure	Upgrade CITRIX to XenApp 6.5	Transfer applications to XenApp 6.5 farm (including SCM servers), and configure PVS 6.1

OPEN PROJECTS 2013

Table 5-6 Open Projects 2013

Title	Description	Phase	Est. Start	Est. Activation
ATV Redesign	Implement enhancements as identified by Admissions/ATV Redesign Group	Plan	12/20/2012	Nov, 2013
Barcode - Med Admin	Implement barcode for Medication Administration	Plan	9/30/2010	11/12/2013 (Pilot)
Enterprise Scheduling & Encounter Model	Implement an enterprise scheduling system that will integrate with multiple department systems (LIS, RIS, etc.) as well as CRIS. Also includes the implementation of an encounter model (old CI-030)	Exec	12/7/2010	Jun, 2014
Genetic Mutation - GeneDx	Support the creation of genetic testing orders and results within SCM, and create an order/result interface between CRIS, LIS, and GeneDx (external lab that conducts genetic mutation tests)	Plan	10/1/2011	Feb, 2014
IntelliSpace ECG Upgrade	Upgrade EKG TraceMasterVue to version C.03, from B.03.00.04	Plan	7/16/2012	TBD
PEFR enhancement	Add functions to the application so that the SWD is in compliance with Regulation: 42CFR Chapter 1 35.66.	Exec	2/8/2013	Sep, 2013
Protrak 1195 Feed	Develop a data feed from PTMS to Protrak for updated protocol information	Plan	1/31/2013	Nov, 2013
Rewrite Surgi	Allow DPM users to access the SACRED privilege information through the web UI instead of the 4D client.	Plan	2/4/2013	10/7/2013
SCM to ARIA Interfaces - NCI-ROB	Implement a SCM Inbound PDF interface from ARIA for documentation and a SCM Inbound interface for Disease Staging data to be put in Health Issues	Initiate	4/24/2013	TBD
<i>TheraDoc Phase 3</i>	<i>Upgrade TheraDoc, replace hardware, implement pharmacy modules, enhance ADT feed for OP encounters and implement Vital Sign, Surgery, and VAD interfaces</i>	<i>Next</i>	<i>5/23/2013</i>	<i>Phase 1 = 8/22/2013; Phase 2 = TBD</i>

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SECTION 6

QUALITY OF SERVICE METRICS

DCRI measures quality of service through multiple measurements across its business areas. Many of these metrics are based on industry standards as a benchmark, but are evaluated with the realization that the Clinical Center is a unique institution whose main focus is medical research.

SYSTEM AVAILABILITY

Managing our systems to keep them up and running 24/7/365 is an important task. Inability to access clinical data for patient care has potentially dangerous consequences. To give clinicians as much time to prepare as possible, we ensure that all planned system downtimes are communicated effectively and in advance for these times when maintenance on the system must be performed. We have the benefit of not having an Emergency Room or Labor and Delivery.

Tracking downtime metrics allows us to review the data for any negative trends that need to be addressed. We track all downs as well as performance degradations as part of our System and Monitoring Process. For each interruption, performance degradation, or system down we track the date and time of the event, the duration of the event, and the resolution. All entries are reviewed by an Executive Leader within DCRI and then reviewed as part of our Technical Review Board Meetings.

All calculations and percentages are based on 24 hour availability: 365 days * 24hrs * 60min = 525,600 min/yr. The DCRI goal for total unscheduled downs is .001% with a total uptime of 99.9%, considering both scheduled and unscheduled downs.

Table 6-1. System Availability Metric

	2010			2011			2012			2013 To Data		
	P	U	Total	P	U	Total	P	U	Total	P	U	Total
CRIS System	.6%	.1%	99.3%	.29%	.01%	99.7%	.14%	0%	99.86%	.194%	0.013%	99.8%
Interfaces	.1%	.1%	99.8%	.07%	.27%	99.66%	.05%	0%	99.95%	.022%	0.022%	99.956%
Network	.4%	.3%	99.3%	.3%	0%	99.7%	.09%	0%	99.91%	0%	0%	100%
File Share				.02%	.01%	99.7%	.02%	.01%	99.97%	.02%	.0%	100%

P = Planned, U = Unplanned

Data Center Specifics	1999	2009	2012
Servers	70	439	760
Relational Database Systems	1	4	4
Disk Storage	4.2 TB	60 TB	80 TB

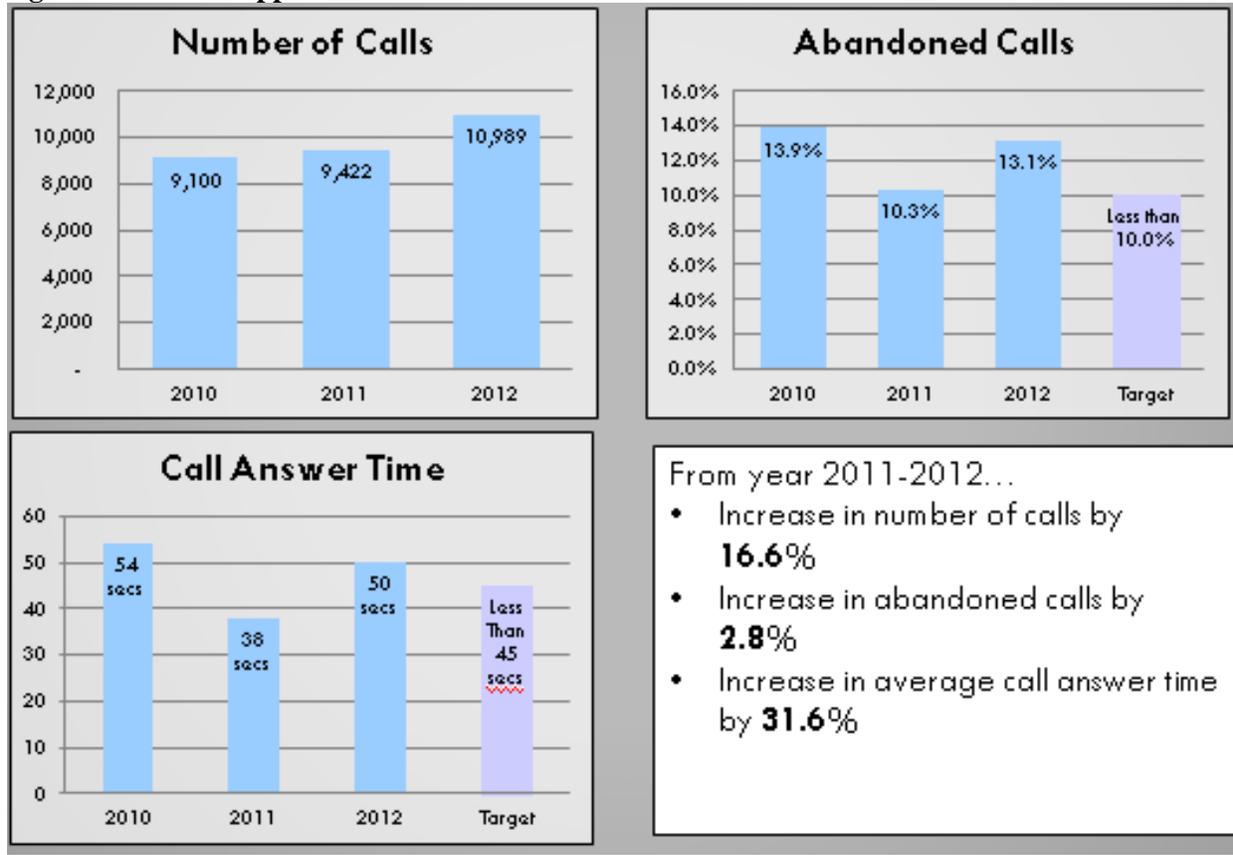
CLINICAL SYSTEM DEVELOPMENT AND SUPPORT

CRIS Support

CRIS Support Call Metrics

The volume of calls to the CRIS helpdesk and the number of tickets opened to request help continued at high levels in 2012. The majority of these calls and help requests included desktop support assistance with hardware, network and printing issues. The number of calls for assistance with the CRIS application consisted of approximately 20% of the help requests. As part of 2013 DCRI Service Center Model CRIS calls will be consolidated into the DCRI Service Center.

Figure 6-1. CRIS Support Call Metric

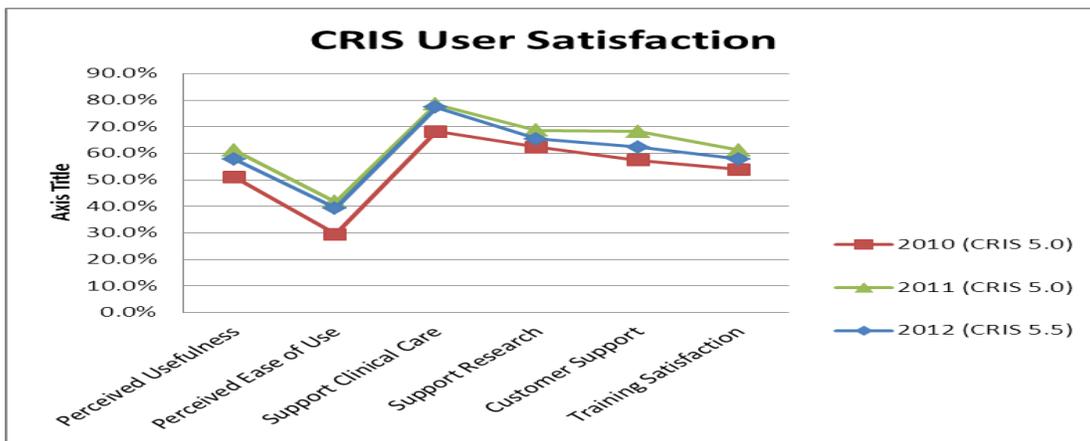


CRIS User Satisfaction

CRIS user satisfaction is assessed annually via a web-based survey sent to all CRIS users. For the 2012 Survey there were 226 responses to the 14 item questionnaire (which was tested for validity and reliability (Fred Davis, 1986)) for the areas of perceived usefulness and perceived ease of use. Additional questions were asked regarding customer support, training, and the systems perceived ability to support clinical care and research. Table 10-2 shows the satisfaction levels from 2010 to 2012.

Table 6-2. CRIS Satisfaction Metric 2010 - 2012

Indicator	Target	Feb 2010 (CRIS 5.0) (N=268)	Dec 2011 (CRIS 5.0) (N=312)	Dec 2012 (CRIS 5.5) (N=226)	Change from 2011
Perceived Usefulness	>80%	51.1%	61.2%	57.9%	- 5.39%
Perceived Ease of Use	>80%	29.5%	41.7%	39.4%	- 5.52%
Support Clinical Care	>80%	68.0%	78.5%	77.4%	- 1.40%
Support Research	>80%	62.0%	68.6%	65.5%	- 4.52%
Customer Support	>90%	57.5%	68.3%	62.4%	- 8.64%
Training Satisfaction	>80%	54.0%	61.2%	57.9%	- 5.39%



These numbers represent the percentage of responses that fell into the categories of Strongly Agree and Agree.

While there has been no significant changes in the values from the survey, we will continue to work with CRIS end-users to help us create a more user-friendly system within the parameters of COTS functionality. We will also continue to identify ways to improve upon customer support and outreach programs for CRIS, and to gather information on how to improve CRIS to meet the user’s workflow and business requirements.

CRIS Training Activities

CRIS training for end-users continues at a high volume with 1470 students trained over the course of last year (2012). Overall satisfaction with training was 80.6% (4.03/5).

Table 6-3. CRIS Training Attendance In Class Training

Class	2010	2011	2012	% change 2011 - 2012
Introduction	657	694	739	+6.5%
Non-Prescriber Order Entry	175	154	189	+22.7%
Clinical Documentation	36	49	53	+8.2%
Clinical Documentation w/ Worklist Manager	137	139	179	+28.8%
Prescriber Course (In-Class)	71	69	73	+5.8%
Prescriber Online2	206	184	225	+ 22.28
Worklist Manager	4	2	2	0
Advanced Training		55	9	-83.6%
ICU Clinical Documentation for Nursing		40		
Totals	1286	1386	1470	+4.8%

Change Management

DCRI has a formal process to manage and track changes to the numerous systems that we support. All changes go through a standard approval process prior to being implemented in our production systems. These changes are tracked from beginning to end in the change management system Serena Business Manager where data can be tracked and monitored.

Examples of simple System Change Requests (SCRs) to CRIS are adding a new or changing an existing medication, protocol order set, or lab test. More complex SCRs involve the transmission of data between CRIS and Ancillary systems, creating scripts to trigger alerts (MLMs), or configuration changes that impact multiple existing order sets. Table 10-4 reviews the CRIS Changes Metrics. Figure 10-2 reviews SCRs within CRIS by Department by System Change Request. Table 10-5 review specific item creation within CRIS.

Table 6-4. CRIS Change Management Metric

Year	Target Turn Around Time	Total Received	Total Open (1)	Closed					Turn Around Time in 5 Day Week
				Completed	Denied	Cancelled	Duplicate	Total Closed	
2006	25	1,997	6	1,819	4	135	33	1,991	40
2007	25	2,052	34	1,888	3	95	32	2,018	26
2008	25	2,105	63	1,977	3	47	15	2,042	23
2009	25	1888	187	1701	4	62	17	1784	15
2010	25	2339	161	2027	5	97	26	2,155	29
2011	25	1733	65	1582	6	60	20	1668	24
2012	25	2485	398	2087	5	42	28	2162	20.5

The target turnaround time of 25 days or 6 weeks was selected based on a 3 week release cycle. Changes once reviewed and approved by the Functional Review Board (FRB) and then are implemented into the CRIS Development environment. The CRIS Development environment is migrated to the CRIS Test environment every three weeks to allow for full integration testing and unit testing and then set for a release.

The turnaround time for 2006 was high based on treating both projects and system changes in a similar manner. 2010 was high based on changes with the release process and the increased number of requests. We now utilize a process to review request for changes and those that are determined to be projects treated separately from SCRs and tracked via the Technical Initiatives and Projects System.

Figure 6-2. CRIS Change Management By Department

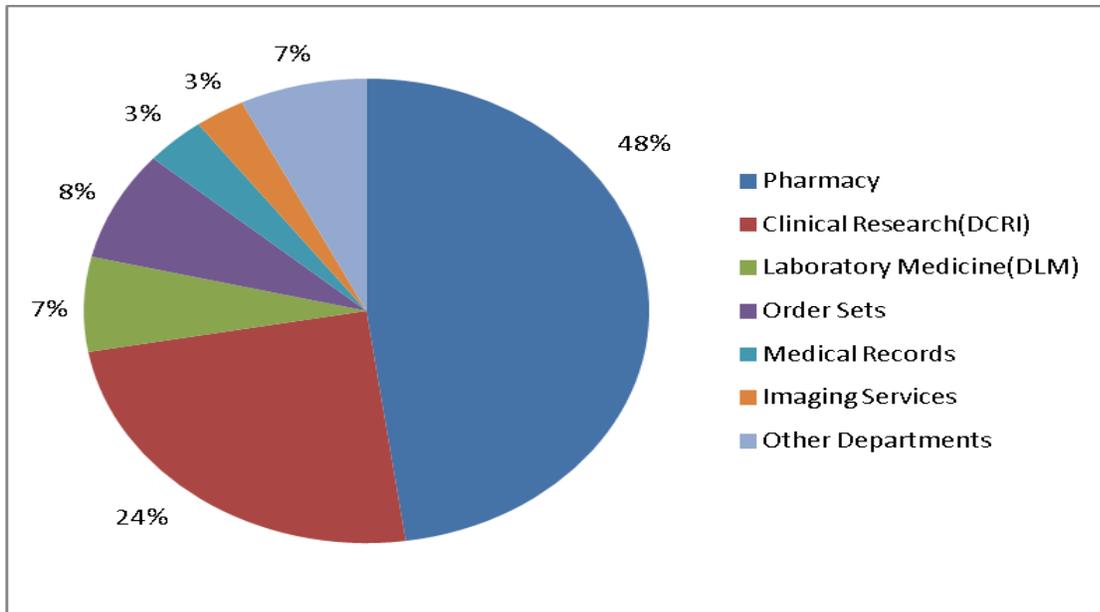


Table 6-5. CRIS Configured Item Creation (by FY)

Items	2010	2011	2012	2013	Total
Protocol Order Sets Created	561	953	717	766	2997
Pharmacy Order Items	118	109	115	118	460
Pharmacy Investigational Order Items	270	307	238	328	1143
Department of Laboratory Medicine Order Items	56	42	11	39	148
Department of Radiology and Imaging Services Order Items	18	49	41	11	119
Department of Transfusion Medicine Order Items	23	3	3	36	65
Other Order Items	31	8	1	19	59
Clinical Documentation Flowsheets	2	2	0	0	4
Clinical Documentation Free Text	34	69	6	11	120
Clinical Documentation Structured Notes	30	24	3	6	63
Total	1148	1566	1135	1334	

TECHNICAL DESKTOP SUPPORT

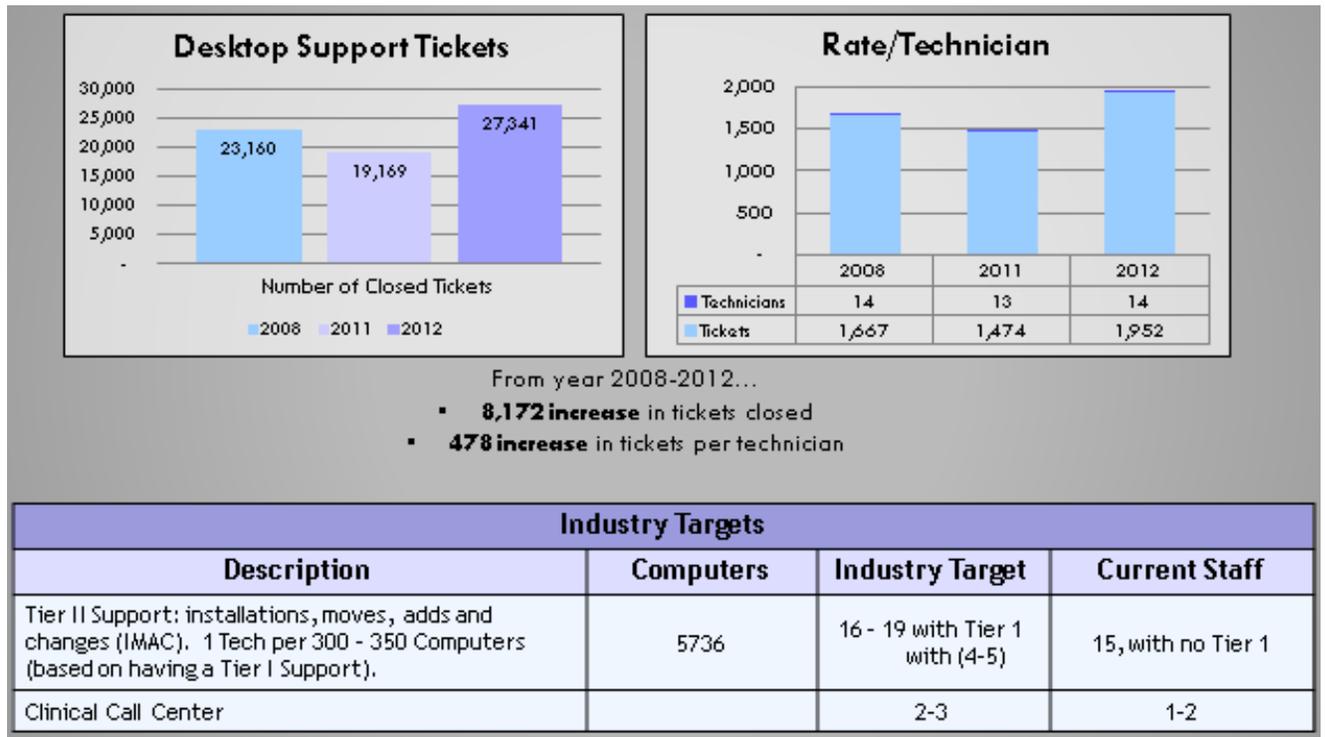
DCRI provides end-user support 24/7 for both technical and clinical issues. From 1999 to July 2013 our Tier I analysts were also our Tier II specialists as well as the ones responsible for coordinating with any Tier III support and the vendor. The changes to Service Center support were presented in Section 10.

Table 6-6. Number of Items Supported

	SunRays	Desktops	Laptops	WOWs	Barcode	Printers	Total
2008	240	3469	628	78	0	1502	5677
2012	300	3427	914	332	519	2078	7270
Change	25%	-1%	46%	326%	N/A	38%	28%

Years	Desktops	Laptops	
< 3	2283	577	
3	586	88	
4*	1084	149	
5	205	48	
6	275	58	
7	89	89	
> 7	181	24	
Total	4703	1033	5736
*Includes 345 WOWs			

Figure 6-3. Technical Desktop Support Metric



SECURITY & PRIVACY

Security and Privacy focuses on the security of all clinical, research and administrative systems and maintains the privacy of sensitive confidential information related to patients, employees and contractors contained therein according to the requirements established by the Privacy Act of 1974. The team is responsible for ensuring the security and privacy of systems under the control of CC departments and third party applications hosted off-site. To maintain security and privacy across systems there is a large amount of operations and maintenance tasks as described in Table 6-7.

Table 6-7. Security and Privacy O&M Metrics

	2011	2012	2013 (YTD)
Security and Privacy Awareness Training completion	100% >2500 staff	100% >2500 staff	100% >2500 staff
SA & As Completed	7	15	9 thus far, 17 planned
System and Third Party Web PIAs Completed	39	50	5 thus far, 89 planned
System of Record Notices audited/modified	0	0	3
Privacy Act Investigations conducted	2	9	8
NIH IRT Portal security incidents	72	146	158
NIH IRT Portal security incidents with PII leaked	2	8	10
Tickets assigned to CC Security Team			402

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SECTION 7

SPACE

There are 21 teams spread over 7 locations at the CC/CRC and two office areas off campus at the Democracy II Building in Bethesda. Sections are located based on their proximity requirements to the CC/CRC and the Data Center as well as space limitations at the CRC/CC. DCRI occupies 14,150 square feet of space, for an average of 134 square feet per person (there are 105 staff members). Table 39 provides a summary of the space by Section followed by individual tables and diagrams. The space and configuration of the Data Center is provided in a separate section.

Table 7-1. Overview of DCRI Space by Section

Section	Number of Locations	Number of People	Total Space	Average Space Per person	Number of Offices	Number of Work Areas
CIO	2	10	1279.4	127.9	8	2
Security & Privacy Office	1	5	1357.1	157.2	1	8
Portfolio Management Office	2	15	1564.1	104.3	5	3
Project Management Office	2	8	418.2	52.3	3	3
Technical Architecture Team	1	4	733.1	183.3	1	3
Test Team	1	3	312.8	104.3	0	3
Clinical Informatics	2	22	2029.6	90.6	17	9
Liaison Team	1	3	255.5	85.2	3	0
Clinical Build Team	2	14	1092.2	78.0	7	3
Support/Training/Analysis	2	5	442.5	88.5	3	0
Technical Operations	2	62	6436.5	103.8	18	45
Server Support & Data Center Operations	2	19	1000.0	52.6	1	18
System Administration	1	10	621.3	62.1	0	10
Systems Monitoring	1	5	210.0	42.0	0	5
Unix Administration	2	2	157.0	78.5	1	1
Network Administration	1	2	132.0	66.0	0	2
Clinical Application	1	19	4000.0	210.5	10	10
Interface Team	1	4	401.5	100.4	1	3
Clinical Database	1	6	940.6	156.8	7	0
Applications Team	1	5	735.4	147.1	3	2
Administrative Database	1	4	697.2	174.3	3	1
Technical Customer Support	1	25	1316.2	52.6	2	16
Tier I Service Center	1	3	126.0	42.0	0	3
Tier II Support	1	17	838.8	49.3	0	12
Specialized Projects	1	5	267.4	53.5	1	3
Budget and Capital Planning	1	3	817.6	142.3	0	5
Program Support	1	2	781.6	390.8	0	4
Inventory & Property Management	1	1	36.0	36.0	0	1
Conference Rooms	2		652.0		4	0
Storage	3		854.4		2	1

Table 7-2. CIO Office Space

Room#	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
6-551	141.7		Office	McKeeby	Jon	CIO
6-5560	95.4		Work Area	McDowney	Sharon	Program Support
	95.4		Work Area	Dassen	Donna	Administrative Officer
1C290A	154.1		Office	Sengstack	Patricia	Deputy CIO, Clinical Informatics
1C290I	138.5		Office	Pitts	James	Chief of Technical Operations
DEM II 950J	192.7		Office	Yarrington	Joyce	Chief Budget and Capital Planning
1C290H	111.7		Office	Herion	David	Chief Medical Officer
1C290B	132.1		Office	Houston	Susan	Chief, Portfolio Officer
DEM II 950L	130.48		Office	Martin	Susan	Chief, Security and Privacy Office
2C262E	87.3		Office	Almazan	Yvonne	Customer Relations

Figure 7-1. CIO Office Space

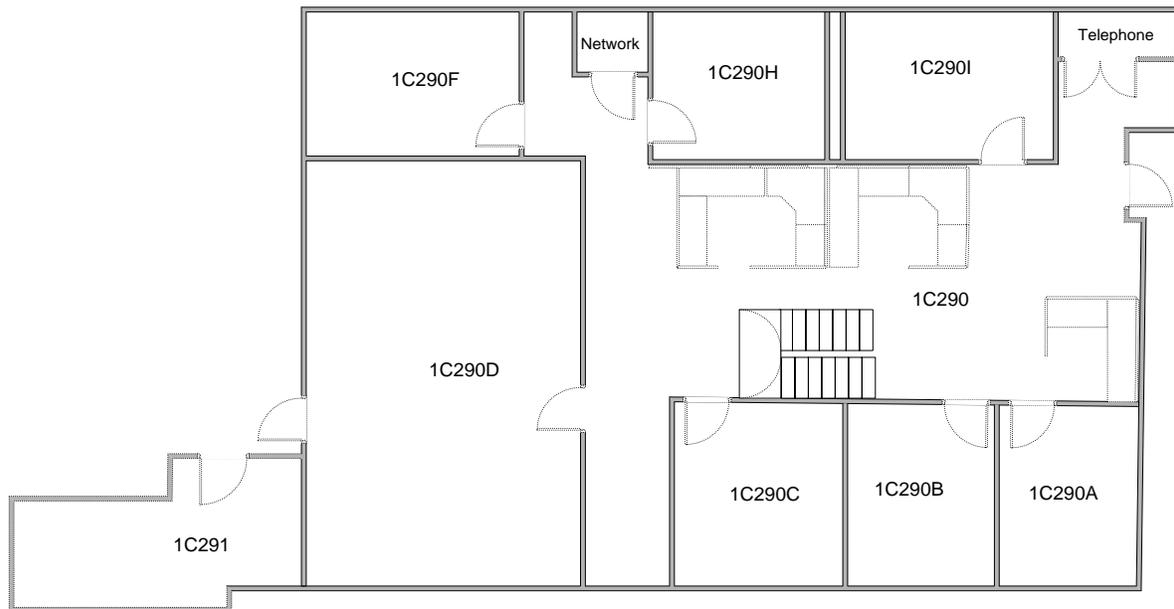


Table 7-3. Security Office

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
950K	142.8	A	Work Area	Chern	Chris	IT Specialist
	142.8	B	Work Area	Brennan	Andrew	IT Specialist
	142.8	C	Work Area	Kingston	Joe	IT Specialist
	142.8	D	Work Area	Lansiquot	Boniface	IT Specialist
	142.8	H	Work Area			
	142.8	I	Work Area			
	142.8	J	Work Area			
	142.8	K	Work Area			
950M	214.7		Office	Dugar	Jothi	ISSO

Figure 7-2. Security Office

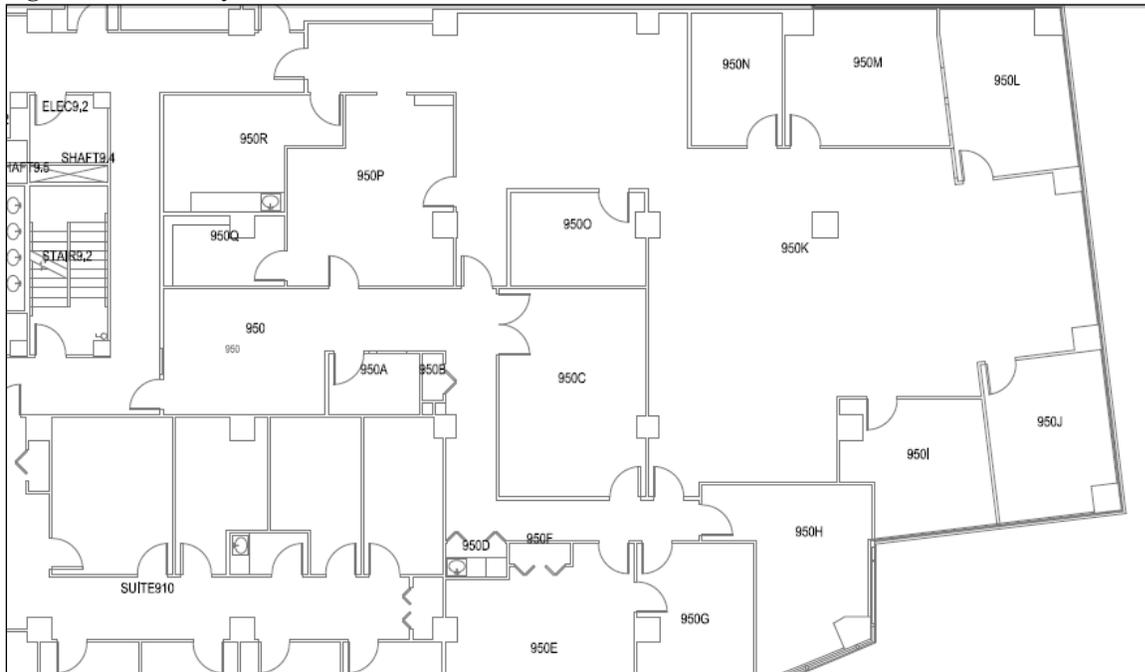


Table 7-4. Portfolio Section: Project Management Office

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
B1S237D	100		Office	Kennedy	Ryan	Chief, Project Management Office
B1S237	33	A	Work Area	Wight	Judy	Project Manager
	33	B	Work Area	White	Nicole	Project Manager
	33	C	Work Area	Vargas	Isolina	Project Manager
2C262I	64.2	A	Office	Nghiem	Mindy	Contractor
	64.2	B	Office	Broydo	Yulia	IT Specialist
950G	95.4	A	Office	Beverly	Carol	IT Specialist
	95.4	B	Office	Mowatt	Sharon	IT Specialist

Figure 7-3. Portfolio Section: Main Project Management Office

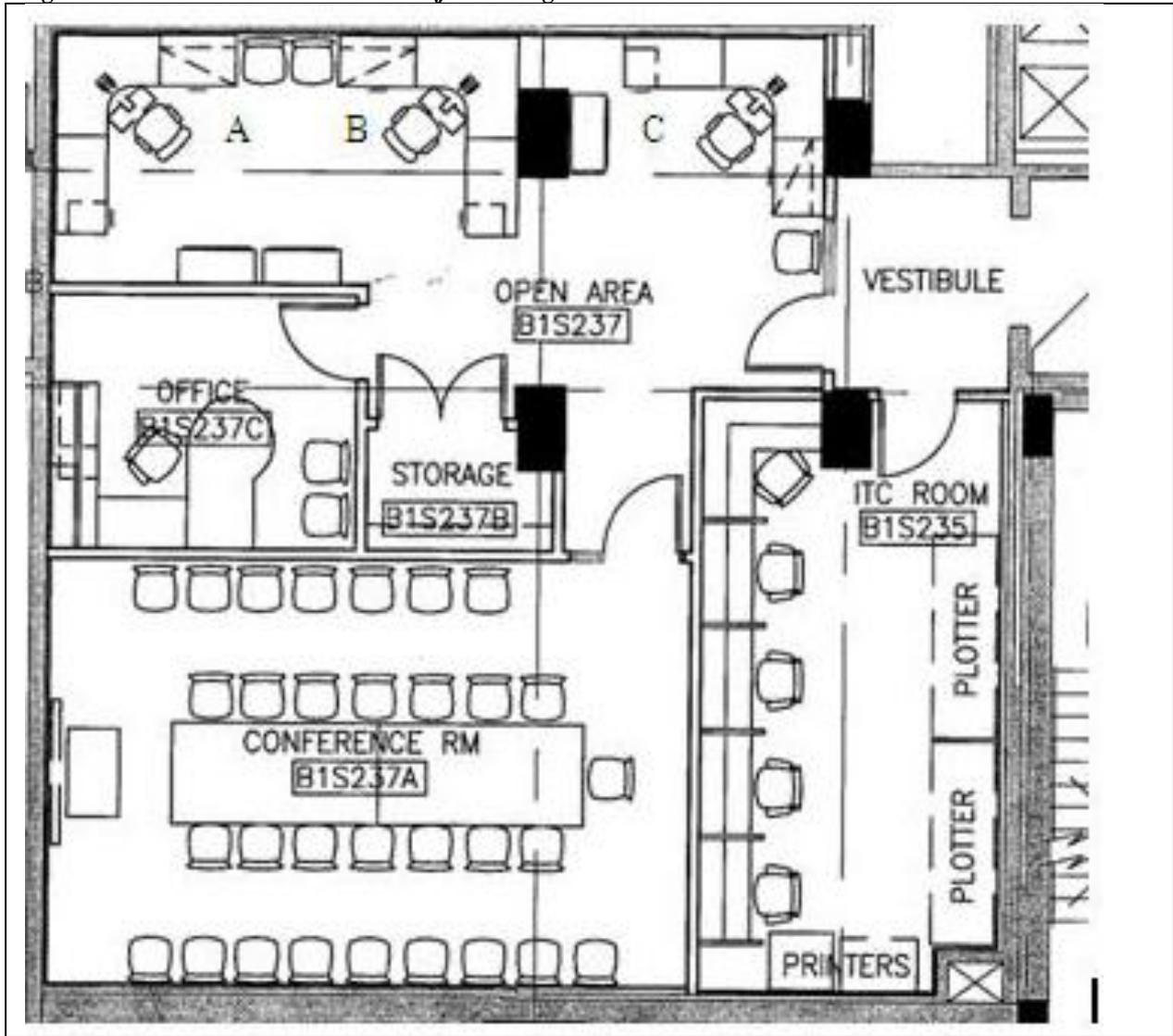


Table 7-5. Portfolio Section: Technical Architecture

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
DII 891	301.7		Office	Bergstrom	Steve	Supervisor, IT Specialist
DII 950P	288.6		Work Area	Adams	Keith	IT Specialist
DII 950	42		Work Area	McKinney	Jeff	Configuration Specialist
DII 950K	142.8	E	Work Area	Stewart	Demetri	IT Specialist

Table 7-6. Portfolio Section: Test Team

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
DII 950N	124.3		Work Area	Preuss	Jeanne	Tester
DII 950I	45.7	A	Work Area	Etin	Inna	Tester
DII 950K	142.8		Work Area	Givens	Ashley	Tester

Table 7-7. Clinical Informatics: Liaison Team; Clinical Build Team; Support/Training/Analysis

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
2C262A	94.2		Office	Carlson	Seth	Supervisor, IT Specialist
2C262B	77.7	A	Office	DiPatrizio	Gary	Contractor
	77.7	B	Office	Skahill	Victoria	IT Specialist
2C262C	57.9	A	Office	Wellesley	Christine	Nurse Informaticist
	57.9	B	Office	Cochran	Kelly	Nurse Consultant
2C262D	122.8		Office	Raju	Mini	Nurse Consultant
2C262F	39.9	A	Work Area			Student
	39.9	B	Work Area			Student
	39.9	C	Work Area			Student
	39.9	D	Work Area			Student
	39.9	E	Work Area	Farnum	Lincoln	Contractor
	39.9	F	Work Area	Godwin	MaryJo	Contractor
	39.9	G	Work Area	Winters	James	Contractor
	39.9	H	Work Area	Triplett	William	Management Analyst
2C262G	120.7	A	Office	Revoir	Josanne	Nurse Consultant
	120.7	B	Office	Siwy	Christopher	IT Specialist
2C262H	120.41		Office	Postal	Susy	Supervisor, Nurse Informaticist
1C290C	74.8	A	Office	Defensor	Rubi	Nurse Consultant
	74.8	B	Office	Smyth	Frankie	Nurse Consultant
1C290F	73.1	A	Office	Briguglio	Claudia	Nurse Consultant
	73.1	B	Office	Menegussi	Lucia	Nurse Consultant
950I	45.7	B	Office	Fink	Tom	IT Specialist
950K	142.8		Work Area	Moyer	Warren	IT Specialist
881	157		Office	Moore	Steve	IT Specialist
885	118	B	Office	Mickey	Frank	IT Specialist
886	101.04	B	Office	Lee	Myoung	IT Specialist

Figure 7-4. Clinical Informatics: Liaison Team; Clinical Build Team; Support/Training/Analysis

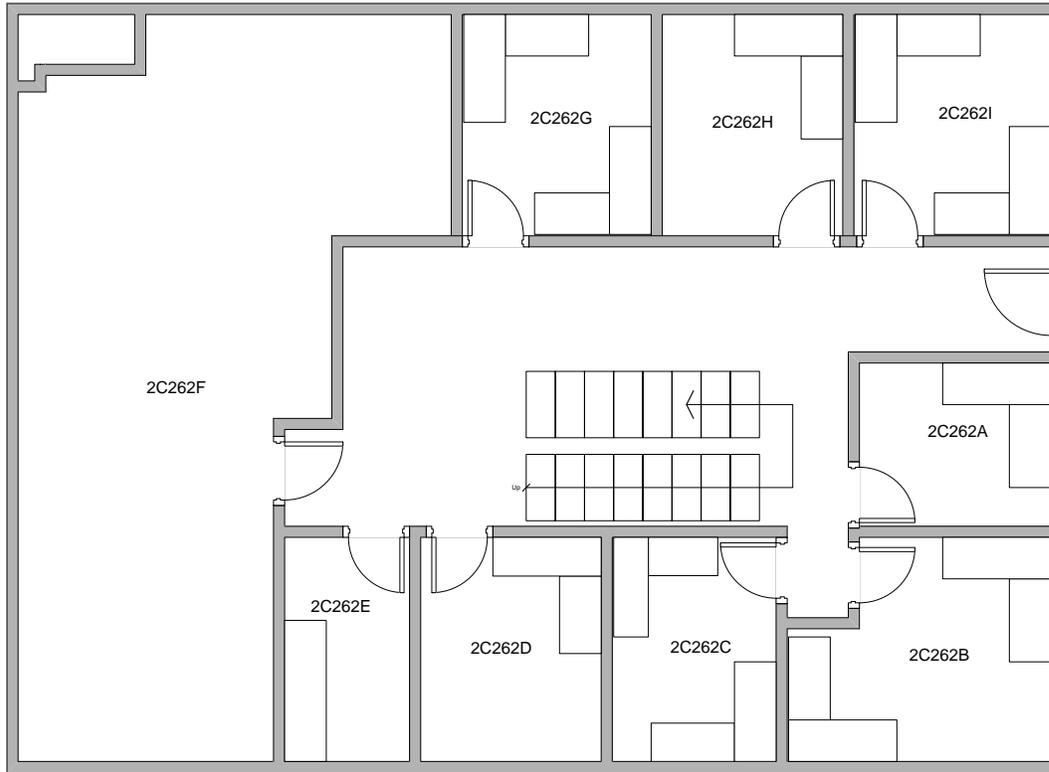


Table 7-8. Technical Operations Section: Clinical Applications 6707 Democracy

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
B1C04	120.3		Work Area	Kocher	John	IT Specialist
B1N243	56	H	Work Area	Bradley	Mark	IT Specialist
	56	J	Work Area	Butters	Doug	IT Specialist
	42		Work Area	Cain	Arthur	IT Specialist
	55	I	Work Area	Dunn	Dempsey	IT Specialist
	42		Work Area	Gregg	Alex	IT Specialist
	52	K	Work Area	Grieb	Barrett	IT Specialist
	77	N	Work Area	Myrick	Todd	IT Specialist
	55	L	Work Area	Snakenberg	Brad	IT Specialist
	66	R	Work Area	Vinh	David	IT Specialist
	42	B	Work Area	Burke	Michael	IT Specialist
	42	A	Work Area	Carter	Pam	IT Specialist
	42	D	Work Area	Ly	Van	IT Specialist
	42	E	Work Area	Redmond	Ray	IT Specialist
	42	G	Work Area	Slade	Gayle	IT Specialist
39	O	Work Area	Klein	Chris	IT Specialist	
884	118		Office	Yenegeta	Tadele	IT Specialist
B1C05A	66	A	Work Area	Chan	Jason	IT Specialist, Network Admin
	66	B	Work Area	Walker	Richard	IT Specialist, Network Admin

Figure 7-5. Clinical Applications, Administration and Interfaces 6707 Democracy



Figure 7-6. Custom Applications and Databases 6707 Democracy

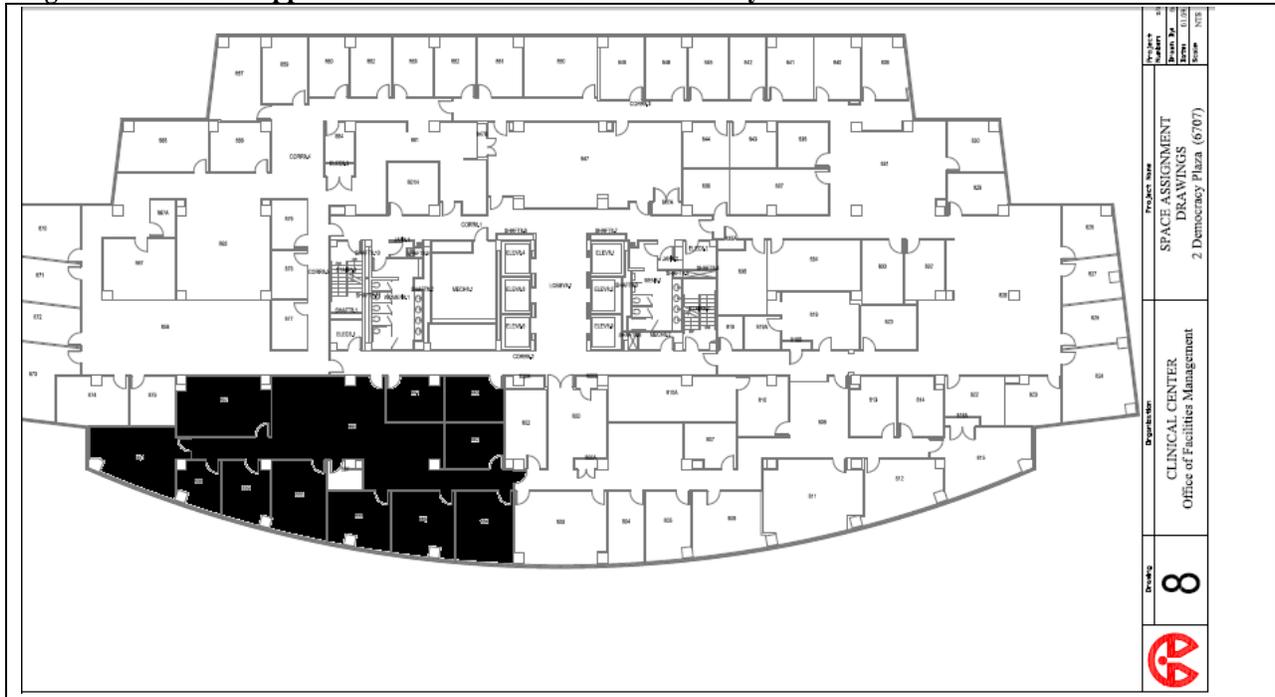


Table 7-9. Technical Operations Section: Clinical Applications 6707 Democracy

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
950	500.7		Work Area			
950E	90.2		Work Area	Blackwell	Stephen	IT Specialist
	90.2		Work Area	Stehr	Robert	IT Specialist
	90.2		Work Area	Ravichandran	Sundari	IT Specialist
	90.2		Work Area			
950H	114.3	A	Office	Nansel	Mike	IT Specialist
	114.3	B	Office	McGann	Mike	IT Specialist
950O	130.9		Office	Liu	Yenshei	Supervisor IT Specialist
880	199.2	A	Work Area	Kadiwar	Sejal	Contractor
	199.2	B	Work Area	Meng	Grace	Contractor
	199.2	C	Work Area	Chen	Grace	IT Specialist
	199.2	D	Work Area			
	199.2	E	Work Area			
882	157	A	Office	Chen	May	IT Specialist
	157	B	Office			IT Specialist
883	157		Office	Barnes	Tony	Supervisor IT Specialist
884	118	B	Office	Farina	Richard	IT Specialist
	118	C	Office			
885	118	A	Office	Lightfoot	Phil	IT Specialist
	118	C	Office			
886	101.04	A	Office	Lee	MC	IT Specialist
888	220	A	Office	Dawson	Tom	IT Specialist
	220	B	Office	Oseth	James	IT Specialist
889	178		Office	Maloney	Tim	IT Specialist
890	121		Office	Kumar	Murali	IT Specialist

Table 7-10. Technical Operations Section: Technical Customer Support

Room #	Square Foot	Seat	Room Type	Last Name	First Name	Employee Title
B2L-104A	110.2		Office	Brown	Bertram	Supervisor IT Specialist
B2L-104	42	A	Work Area	Tam	Tran	IT Specialist
	42	B	Work Area	Morton	Tom	IT Specialist
	42	C	Work Area	Patel	Manjula	IT Specialist
	42	D	Work Area	Joseph	Anthony	IT Specialist
	42	G	Work Area	Khatri	Mukesh	IT Specialist
	42	H	Work Area	Schuler	Alison	IT Specialist
	42	I	Work Area	Eng	Theresa	IT Specialist
	42	K	Work Area	Smith	Sylvester	IT Specialist
	42	L	Work Area	Clark	Eric	IT Specialist
	42	M	Work Area	Williams	Les	IT Specialist
B1S223	78	A	Work Area	Lindsay	Sabrina	IT Specialist
	78	B	Work Area	Rodgers	Sandra	IT Specialist
	78	C	Work Area	Dutcher	Patty	IT Specialist
	78	D	Work Area	Smith	Sylvester	IT Specialist
B1S224	89.4	A	Work Area	Lyon	Michael	IT Specialist
	89.4	B	Work Area	Herrick	Mike	IT Specialist
B1S224B	105.4	B	Office	Hernandez	William	Supervisor IT Specialist, Special Projects
B1S224C	107.9	C	Work Area	Logan	Larry	IT Specialist
2C262	39.9		Work Area	Doyle	Robert	IT Specialist
Radiology Dept.				Donovan	Devery	IT Specialist
Teleworker				Miamee	Golnar	IT Specialist
DLM				Pannell	Lovelee	IT Specialist
				Saeed	Amin	IT Specialist

Figure 7-7. Systems Administration and Data Center Management

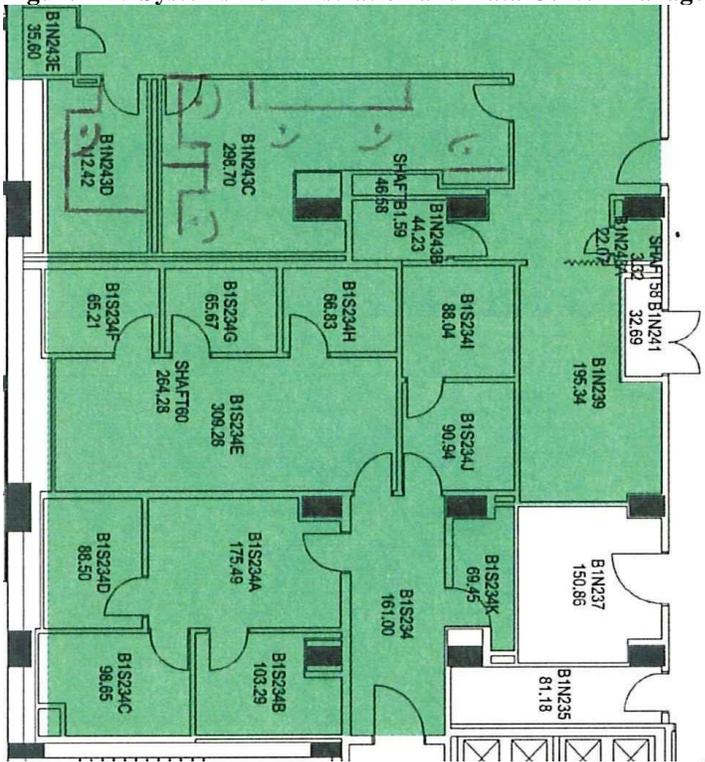


Figure 7-8. Systems Administration and Data Center Management

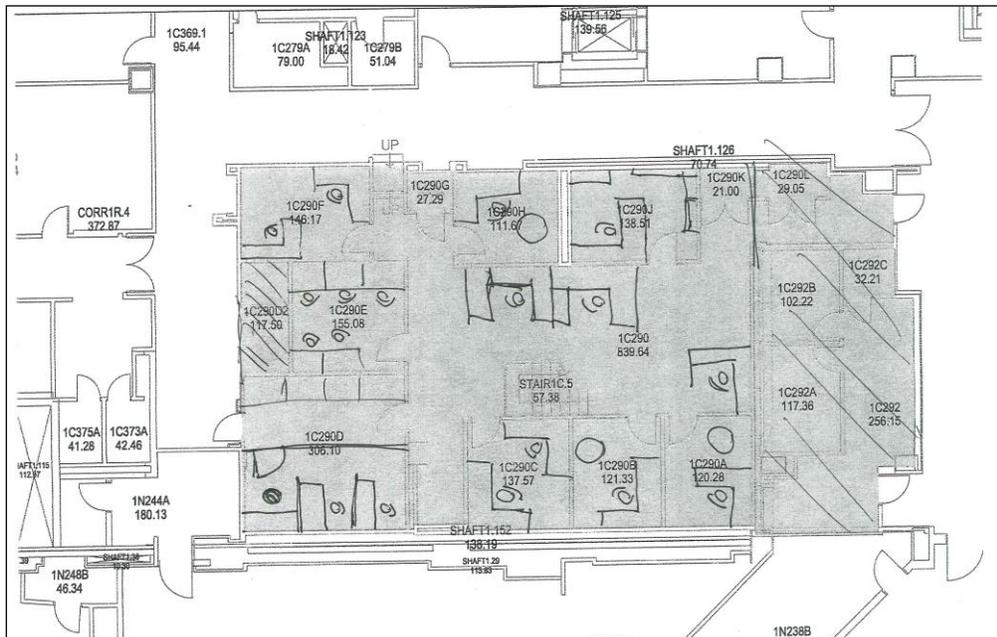


Table 7-11. Budget and Planning Section

Room #	Square Ft.	Seat	Room Type	Last Name	First Name	Employee Title
1C290	195.4	A	Work Area	Abner	Cleo	Program Support
	195.4	B	Work Area	Jarquin	Maria	Program Support
	195.4	C	Work Area			Student
	195.4	D	Work Area			Student
B2S231	100		Work Area	Cox	Siron	IT Specialist

Table 7-12: Conference Rooms and Storage

Room #	Square Ft.	Seat	Room Type	Title
892	308		Conference	
B1C02	192.3		Conference	
B1S237B	100		Conference	
1C290D	531		Education	Training
950F	14.4		Storage	Closet
1C291	160		Storage	Closet
B2S231	680		Storage	
B1S235	264		ITC	

Figure 7. Systems Monitoring

