



NCI Community Cancer Centers Program Program Overview – St. Joseph, Orange

A. Name and Location of Hospital: St. Joseph Hospital of Orange

1100 West Stewart Drive
Orange, CA 92863

B. Name of Cancer Center: St. Joseph Hospital Cancer Center and Cancer Institute

C. Identify PI and key personnel with contact info (very brief bios) for each of the pilot focus areas:

- **Disparities**
- **Clinical trials**
- **IT**
- **Biospecimens**
- **Quality of Care**
- **Survivorship**

Larry Ainsworth, President/CEO

Larry Ainsworth is President and Chief Executive Officer of St. Joseph Hospital, a 412-bed general acute-care hospital. He has held this position since November 1994. St. Joseph is the fourth busiest surgical service in the State. With its new Da Vinci robotic surgical technology, the nation's first total hysterectomy and the County's first mitral valve replacement were performed. The Hospital's Emergency Department serves nearly 100,000 patients each year and its open-heart surgery program is the busiest in Orange County. For four years Mr. Ainsworth had responsibility for managing Children's Hospital of Orange County and CHOC at Mission Hospital. With the Board and management team at CHOC, St. Joseph Hospital assisted in restoring both CHOC hospitals to operational and financial health. Prior to joining the staff at St. Joseph Hospital, Mr. Ainsworth held the position of Executive Vice President and Chief Operating Officer at Hoag Memorial Hospital Presbyterian in Newport Beach, California. Earlier in his career, Mr. Ainsworth served as Senior Vice President and Administrator of Women's and Children's Hospital at Long Beach Memorial Medical Center in Long Beach, California, and held various positions at Desert Hospital in Palm Springs, California. Mr. Ainsworth holds a Master of Public Administration degree with specialization in Health Services and Finance from Brigham Young University. His Bachelor of Science degree was also attained at Brigham Young University.

Tom Hill Pharm.D, VP Operations

Tom Hill is a hospital executive with thirty-two years of hospital operations experience. He is currently Vice President of Operations at St. Joseph Hospital. Areas of responsibility include all Support Services, Clinical Ancillary Departments (Pharmacy, PT/OT/Speech), Outpatient Clinical Services (Cancer Center, Renal Center, Wound Care Center) and Construction. Prior to joining the St. Joseph Health System, Mr. Hill spent 26 years at St. Mary's Medical Center in Long Beach with progressive leadership responsibilities in the areas of Pharmacy, Quality Management, Utilization Management, Risk Management/Safety and Operations (all Support and Ancillary Services). He holds a Bachelor's Degree in both Biology and Pharmacy and earned his Doctorate Degree in Pharmacy from the University of Southern California.

Jim Padova MD, Medical Director, Cancer Center and Cancer Institute

Dr. Padova has been a practicing physician for almost 40 years. He currently serves as the Cancer Program Medical Director for St. Joseph Hospital. This position directs key program initiatives,

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including tumor-specific objectives, technology evaluation and acquisition, clinical research, the use of evidence-based patient guidelines, as well as measuring, reporting, and improving patient outcomes. Dr. Padova earned his Pre-Medical degree from St. Joseph University and his Doctorate at Hahnemann Medical University in Philadelphia. He began his residency on the East Coast, and then came west in 1969 to practice hematology, oncology and internal medicine. Over that time, he has remained an active member of the medical community in Orange County. His academic pursuits include lecturing as an Associate Professor of medicine at the University of California, Irvine.

Jay Harness MD, Medical Director, Comprehensive Breast Center Principle Investigator, NCCCP Pilot Program

Jay.Harness@stjoe.org

Dr. Harness is a practicing surgeon with thirty-two years of experience as a Medical Director. He currently serves as Medical Director for the Comprehensive Breast Center at St. Joseph Hospital. As Primary Investigator for the pilot project, he has authority to lead the cancer center's various clinical and supportive care activities for the pilot project. Dr. Harness received his Bachelor's Degree from the University of Arizona and his Doctorate from the University of Michigan Medical School. Afterward, he completed a program for Health Systems Management at Harvard University. He has been invited to lecture in the Schools of Medicine at the University of Michigan, UC Davis, and Tufts University. Dr. Harness also serves as a member of the Healthcare Disparities Task Force and Quality of Care Outcomes Committee.

Nancy Harris, Administrator, Cancer Center

Nancy.Harris@stjoe.org

Nancy Harris is an experienced service line manager with 16 years experience as a Cancer Center Administrator, strong leadership and administrative skills, as well as healthcare grant management experience. Areas of responsibility include administration for the entire cancer service line operations, Cancer Institute and construction of a new state-of-the-art 87,000 sq. ft. center opening in 2008. The Cancer Institute includes site-specific and specialty cancer programs for Breast, Lung, Prostate, Colorectal, Melanoma, Head and Neck, HPCT/BMT, and Cancer Genetics. Prior to joining St. Joseph, Ms. Harris spent a number of years managing oncology services at throughout centers in Gainesville, Georgia and Sacramento, California. She holds a Bachelor's Degree in Biology, Medical Technology and earned her Master's Degree in Public Administration, Health Services Administration from the University of Southern California. Ms. Harris serves as the Pilot Program Administrator.

Alice Park, Operations Coordinator, Cancer Center

Alice.Park@stjoe.org

Ms. Park is currently the Operations Coordinator at the Regional Cancer Center. She has a unique combination of clinical, legal, and administrative background and experience in healthcare operations and marketing. Ms. Park holds a Bachelor's Degree in Physiological Science from UCLA and a Doctorate of Dental Surgery from Columbia University. Additionally, she earned a joint Master of Health Administration and Juris Doctorate with a concentration in healthcare. Ms. Park serves as the Project Coordinator for the pilot program.

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Maureen Mikuleky, Director, Cancer Services

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Ms. Mikuleky is a research focused, self-motivated registered nurse with over fifteen year's experience in healthcare leadership. Her background includes examining systems and developing processes to ensure compliance with regulatory requirements and standards of care. As Director of Cancer Services at St. Joseph Hospital, she is responsible for Cancer Registry, Radiation Oncology, Cancer Center Infusion Center, Inpatient Oncology Unit, and the Bone Marrow Transplant Program. Notably, she received the Excellence Values in Action Core Values Award last year for her service at St. Joseph Hospital. Maureen received both her Bachelor's Degree with Distinction and Master's Degree in Human Resources Management at the University of Redlands. Additionally, she has diplomas in nursing from Fitzgerald Mercy Hospital and Kaplan College. Ms. Mikuleky serves as administrative lead on the Patient Navigation Working Group.

Maria Gonzalez, Manager, Cancer Research

MariaI.Gonzalez@stjoe.org

Ms. Gonzalez is the Cancer Research Manager for the Cancer Center at St. Joseph Hospital in Orange. Her duties include managing growth and development for the Cancer Research Program, maintaining and expanding the research focus of the Cancer Center and providing research oversight for all Cancer Center clinical studies. Ms. Gonzalez works closely with Medical Director, Cancer Center Administrator, and investigators from the multidisciplinary teams in the planning of future clinical trials (Phase II/III studies). Ms. Gonzalez holds a Bachelor's Degree in Biological Anthropology from University of California, Los Angeles. After graduation, she earned her certification as a Nursing Assistant then completed coursework in Anatomy and Physiology at UCLA and Medical Billing at Santa Monica Community College. Ms. Gonzalez serves as administrative lead for the Clinical Research task Force and chair of the Health Disparities & Outreach Task Force.

Loretta Mann, PSC Site Manager

Loretta.Mann@stjoe.org

In her current position as Director of Information Systems for Perot Systems, Ms. Mann focuses on Technical Infrastructure Design for new Patient Care Centers, Development of IS Strategy and preparation of Staff and Site for Care Redesign, Community Connectivity and Process Improvement implementations for St. Joseph Hospital. Ms. Mann established her own company in 1992 specializing in medical management, litigation and applications design. It grew to become the largest establishment of its kind in California. In 1996, that business became Med Pay, a software design company that developed online applications for Managed Care Organizations and Provider Organizations. Med Pay was awarded two major contracts, one by a Hospital Association with over 47 locations and the second for a PPO with over 200 Physician members. Ms. Mann serves as the administrative lead for the Electronic Medical Records System Integration.

Aaron Sassoon MD, PhD, Pathologist

Aaron.Sassoon@stjoe.org

Dr. Sassoon is board certified in anatomic pathology, clinical pathology and hematopathology and serves on several Cancer Institute multidisciplinary site-specific teams. He is one of six pathologists, all double board certified, based at St. Joseph Hospital. Dr. Sassoon received both his Bachelor of Science in Biochemistry and Doctor of Philosophy in Cellular Biology from the University of California, Los Angeles, followed by his Doctorate of Medicine from the University of Southern California. Dr. Sassoon will be the Chair of the Biospecimen Repository Task Force.

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May Lin Tao MD, Medical Director, Radiation Oncology

May.Tao@stjoe.org

Dr. Tao is Medical Director of Radiation Oncology at St. Joseph Hospital and an adjunct member of the John Wayne Cancer Institute. Notably, she has served as a professor at UCLA's School of Medicine and guest lecturer at California State University, Long Beach. The number of grants and honors she has received are only exceeded by her list of published writings. Dr. Tao graduated cum laude with a Bachelor's Degree in Biology at Yale College in New Haven, Connecticut. She went on to earn her Doctorate from New York School of Medicine and an MSPH in Health Services from UCLA School of Public Health. Dr. Tao serves as chair of the Quality and Outcomes Committee.

D. Describe the model for medical staff for cancer center (e.g. employed, private practice, contracts, specialty company contract, combination).

Physicians supporting the Cancer Center and Cancer Institute programs are in private practice throughout the community of Orange, CA and surrounding areas. The Medical Director for the Cancer Center, as well medical directors for the Cancer Institute programs, hold administrative contracts with the hospital.

E. Provide the number of physicians in the cancer program – note cancer program specific medical staff credentialing if applicable.

The Cancer Program operates with the support of 112 physicians, primarily specialists. A physician member in good standing with the SJO medical staff may provide cancer care within the institution subject to special credentialing provisions for procedures, medical disciplines, etc. Those physicians who are members of and supported by the Cancer Institute however, have agreed to, and are bound by, **Cancer Institute Physician Conditions of Participation**. These conditions outline requirements including site-specific tumor conference attendance, clinical trials participation, Human Subjects Protection education, multidisciplinary diagnostic evaluation and treatment planning, patient care guidelines adherence requirements and treatment of un-/underinsured patients as part of the hospital's outreach efforts. Furthermore, physicians interested in participating in selected Cancer Institute programs must comply with additional conditions established by those specified clinical teams. A summary copy of the SJO Cancer Institute's Conditions of Participation is included as an attachment.

F. Describe multi-disciplinary care model.

The SJO Cancer Institute began in 2003 to improve linkages and coordination of care among all healthcare professionals involved in delivering cancer care services to a single individual. The movement toward tumor-specific multidisciplinary care focused on cancer care coordination; reducing the time from diagnosis to initial treatment; multidisciplinary case conferencing; evaluation and adoption of care guidelines; information dissemination through conferences; journal clubs; and educational conferences; selection, analysis and improvement of clinical outcomes; and development of comprehensive program services including access to a wide range of clinical trials.

SJO has organized its Cancer Institute into six tumor or site-specific programs (breast disease, colorectal disease, lung cancer, prostate cancer, melanoma, and head & neck cancers); one program devoted to individuals at high risk for genetic cancers and another dedicated to HPCT/Bone Marrow Transplant related services. Within each program, an established team of specialty based physicians as well as clinical and support staff address clinical care, research and program development to ensure clinical excellence and comprehensive services to meet the needs of their specific patient populations.

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Seven (7) nurse navigators and two (2) genetic counselors provide the link between the primary care physician or diagnostician and the oncologists (including surgeons), as well as facilitating the multidisciplinary coordination arrangements for the patient. The Nurse Navigators are available to cancer patients to explain treatments, options, next steps, and to assist them in coordination of care between various private practice offices and the complex outpatient cancer care setting. They become a reliable source for information and services that enable SJO to deliver holistic care (including psychosocial, emotional, financial, and spiritual support). Nurse Navigators also play a role in outreach community education and identifying patients who may be eligible for research trials.

Site-specific and general cancer conferences are conducted for discussion of newly diagnosed or suspected cancer cases, those with recurrent cancers and cases where treatment dilemmas have surfaced. A team of clinicians including surgeons, medical oncologists, radiation oncologists, pathologists, radiologists, genetic counselors, patient navigators, palliative care specialists and others meet regularly (sometimes with the patient) to develop the best multidisciplinary plan for treatment. NCCN guidelines are used for cancer evaluation and care guidance, available and appropriate clinical trials are addressed in the discussion and other care needs such as supportive care, are addressed in the conference.

The vision of St. Joseph Hospital Cancer Institute is to attain the highest level of clinical excellence while providing an exceptional patient experience. To realize this vision, a true partnership must exist among the Hospital and the physician members of the Cancer Institute. Physician members contribute clinical expertise in the form of participation in multidisciplinary conferences, cancer research, and technology planning and program development. They also share information contributing to measurable and desirable patient and performance outcomes, and agree to service and communication provisions that further achievement of the exceptional patient experience. In turn, St. Joseph Hospital commits programmatic resources to members in the form of marketing and website promotion; patient and program staff and resources; and clinical research support. This mutually beneficial relationship is articulated in the Cancer Institute's Conditions of Participation.

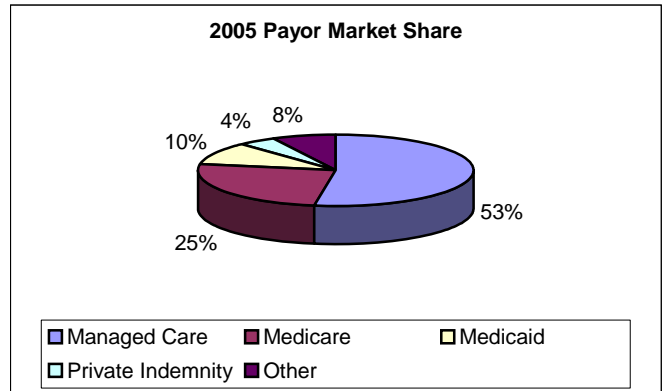
G. Provide a brief overview of community demographics.

St. Joseph Hospital is the dominant provider in the Primary Service Area (PSA) of greater Orange County for oncology, cardiovascular, cardiac surgery, GI, general surgery, gynecology, invasive cardiology, nephrology, neurosurgery, orthopedic, peripheral vascular disease, urology, and women's services. Orange County, encompassing approximately 700 square miles, is located between Los Angeles and San Diego. It is bordered by both the San Bernardino Mountains and the Pacific Ocean (42 miles of coastline). The hospital's PSA is a dense urban population with a diverse ethnic composition: 54% majority of Latinos, 26% Caucasian, 17% Asian (predominantly Vietnamese) and 3% other ethnicities. In 2007, there will be an estimated 1.29 million people residing in the PSA. Growing at a rate of 1.2 percent per year, the population is expected to reach over 1.35 million by 2010. A combination of growth and development in dense family housing is taking place within and areas immediately surrounding the PSA while outlying areas continue to develop single-family housing. The population in the PSA will continue to become more ethnically diverse over the next three years as well. Latinos and Asians are expected to increase by as much as 1.5 percent over the next three years, while Caucasians are expected to decline by 2.6 percent. Considering the rapid growth of the Latino and Asian populations, understanding their health needs will be crucial for service line development at SJO.

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Cancer is the leading cause of death among the Asian population, while it is ranked second behind heart disease for Latinos, Caucasians and other ethnicities. For Latinos in our service area, the overall incidence of cancer is lower, however, Latinos are more likely to develop viral-induced cancers such as cervical cancer or liver cancers linked to hepatitis viruses. Low rates of cancer screening make diagnosis at more advanced stages of the disease when fewer treatment options are available resulting in higher a mortality rate for both Asians and Latinos.

The majority of patients in the PSA continue to fall under the category of Managed Care with a 53 percent share of the market. Traditional Medicare encompasses about 25 percent of the market and Medicaid 10 percent. At the low end is Private Indemnity with 4 percent and 8 percent falling under the category of Other.



H. Describe the philosophy on community outreach and list five major activities to reach disparate populations – note if the organization participates in a formal and ongoing community coalition to address unmet health need.

As a values-based organization, St. Joseph Health System strives to provide healthcare services within an environment of dignity, respect and compassion. St. Joseph Hospital operates with an Administrative Policy on patient financial assistance, which states, “We believe that as a health service organization we have a social responsibility and moral obligation to make quality health services accessible to the medically poor.” Indeed, as other institutions (and their affiliated physicians) have changed their charitable care policies, SJO remains one of the few treatment venues available within a significant service area.

This division, led by the Vice President of Mission Integration, employs more than 70 FTEs. The division’s FY 2006 budget was \$7M. Of this amount, more than \$2M was designated for care for the poor. At least eighteen (18) programs are devoted to the underserved. Addressing healthcare disparities in our service areas is the responsibility of SJO’s Community Benefit Committee (a sub-committee at the Board of Trustees level). This Committee is responsible for approving the Care of the Poor budget, reviewing new and on-going programs to ensure the mission is being addressed, and assuring that charity care is an integral part of the hospital’s overall strategic planning.

Historically, SJO is a key organizer and manager of healthcare partnerships and collaborations. The hospital often provides required strategic planning, programmatic and operational oversight to these community programs that involve multiple agencies. At present, no formal community models or coalitions (that involve clear infrastructure and IT links) among independent facilities or community agencies have developed in this southern California region. SJO, as well as affiliated physicians (through their Conditions of Participation), do participate in several collaboration models.

- SJO operates five (5) Community Clinics that serve the uninsured. La Amistad de Jose Family Health Center is a ‘fixed site’ clinic and is the medical home to over 3,000 uninsured residents; it also serves as the dental home for over 2,000 residents. In addition to providing cancer care for this population, a screening program has been initiated over the last year for

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colorectal cancer. Colorectal surgeons in partnership with the hospital have partnered in a screening colonoscopy program for asymptomatic La Amistad patients.

- Puente a la Salud operates four (4) mobile clinics to provide medical, dental and vision services for 2,000 uninsured farm workers and their families. Puente a la Salud also provides dental care for more than 1,500 adults and 1,000 children and vision services for 1,900 patients. These clinics have a combined operating service history of thirty years.

SJO maintains strong working relationships with a several community and national agencies and supportive care groups to provide support and services focused on cancer patients. These organizations include American Cancer Society, Breast Cancer Angels, BCEDP, Vietnamese American Cancer Foundation, Y-Me National Breast Cancer Support, Center for Cancer Counseling, the American Diabetes Association, the Community Action Partnership, Maternal Outreach Management Systems (MOMS), and the American Heart Association.

Most recently SJO contributed its resources and expertise in three major countywide collaborative efforts:

- Orange County Children’s Health Initiative. The coalition’s purpose is to develop strategies and program to enable all children to be insured for healthcare. The three Orange County-based SJHS hospitals joined with the SJHS Foundation to invest \$3M over three years to expand enrollment and retention of children in health insurance programs with SJO as the lead agency. Nearly 9,000 uninsured children were enrolled in insurance programs in its 1st year.
- “Together As One” Collaboration. Funded by the Tobacco Settlement Revenue through the Coalition of Orange County Community Clinics, this collaborative was formed to provide dental treatment to school-aged children. SJO is the lead agency for this group that includes six (6) community clinics.
- The Pediatric Dental Care Collaborative. Funded by the Children & Families commission of Orange County, this organization provides dental education, screening, and treatment to children from babies to those 5 years old.

California operates two state-funded initiatives, primarily to encourage screening and early diagnosis of cancer. These initiatives include BCEDP (Breast Cancer Early Detection Program) and IMPACT (IMProving Access, Counseling & Treatment for Californians with Prostate Cancer). IMPACT will pay for prostate cancer treatment for up to 12 months for qualified individuals. SJO is a strong partner in both these programs, as it is one of the few remaining hospitals participating as a “take all comers” provider.

SJO has noted significant increases in the number of State-funded BCEDP screening and diagnosed cases. Mammography cases have increased 71% from 2004 to 2006. The number of visits (or encounters) to SJO clinics for women diagnosed with breast cancer has increased more than 1000%, going from 20 visits/encounters cases in 2004 to more than 300 in 2006. SJO staff traces these increases directly to providers who are less willing to accept BCEDP patients.

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I. 2006 new cancer cases – provide in RFP format.

Disease Site (<i>create separate rows as necessary</i>)	Newly Registered Patients
Head and Neck (lip, oral cavity, pharynx, eye, orbit)	30
Digestive System (esophagus, stomach, small intestine, colon, rectum, anus, liver, pancreas)	231
Respiratory (nasal/sinus, larynx, lung/bronchus)	155
Blood and Bone Marrow (leukemia, multiple myeloma, other)	60
Bone (Primary)	3
Connective Tissue	3
Melanoma	46
Other Skin Cancer	9
Breast Cancer (male and female)	359
Female Genital (cervix, ovary, other)	109
Male Genital (prostate, other)	111
Urinary System (kidney, bladder, other)	104
Brain & CNS (benign, malignant, other)	29
Endocrine System (thyroid, other)	54
Lymphatic System (NHL, Hodgkin's lymphoma)	71
Unknown Primary	33
Other/Ill-defined	1
TOTAL:	1408

J. 2006 patients on clinical trials – provide in RFP format.

Sponsor (NCI/other)	Site	Title	Date Opened	Date Closed	Type	2006
SONOCINE	Breast	Semi Automatic Bilateral Whole Breast Sonography and screening mammography	22-Sep-03	26-Jun-06	Screening	3
NAVISCAN	Breast	Prospective Clinical Trial of High Resolution Positron Emission Tomography with FDG	27-Sep-04	21-Dec-06 closed to accrual	Diagnostic	0
NSABP/ RTOG	Breast	A Randomized Phase III Study Of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) For Women With Stage 0, I, Or II	25-Apr-05	Open	Treatment	3

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Sponsor (NCI/other)	Site	Title	Date Opened	Date Closed	Type	2006
		Breast Cancer				
SWOG	Breast	A Phase III Trial of Continuous Schedule AC + G, versus Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer	31-Jan-05	Open	Treatment	1
NSABP	Colorectal	A Phase III Clinical Trial Comparing Infusional 5-Fluorouracil (5-FU), Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks With Bevacizumab to the Same Regimen Without Bevacizumab for the Treatment of Patients With Resected Stages II And III Carcinoma of the Colon	22-Nov-04	6-Oct-06	Treatment	3
UCSF	Rectal	Timing of Rectal Cancer Response to Chemoradiation	29-Aug-05	Open	Treatment	1
ACOSOG	Colorectal	A Phase II Trial of Neoadjuvant Chemoradiation and Local Excision for uT2uN0 Rectal Cancer	24-Apr-06	Open	Treatment	0
COH	Hereditary Risk	Molecular Genetics Studies of Cancer Patients and Their Relatives	24-Nov-03	Open	Genetics	98
SWOG	Leukemia	Leukemia Centralized Reference Laboratories and Tissue Repositories, Ancillary	23-Dec-02	Open	Ancillary	0
SWOG	Leukemia	Cytogenetic Studies in Leukemia Patients	23-Dec-02	Open	Ancillary	0
SWOG	Lung	Lung Cancer Specimen Repository Protocol Ancillary Study	28-Jul-06	Open	Ancillary	0
SWOG/ ECOG	Lung	Phase III Chemoprevention Trial of Selenium in Resected NSCLC	22-Nov-04	Open	Treatment	0
PI Initiated / Regional Cancer Center	Lung	Evaluation of the Validity of in vitro Drug Resistance Assay Test-Directed Chemotherapy Treatment in Non-Small Cell Lung Cancer	28-Jun-04	Open	Treatment	1
RTOG/ SWOG	Lung	Phase III Randomized Trial of Preoperative Chemotherapy versus Preoperative Concurrent Chemotherapy and Thoracic Radiotherapy Followed by Surgical Resection and Consolidation Chemotherapy in Favorable Prognosis Patients with Stage IIIA (N2) Non-Small Cell Lung Cancer	29-Aug-05	Open	Treatment	0

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Sponsor (NCI/other)	Site	Title	Date Opened	Date Closed	Type	2006
UCSF	Melano ma	Sentinel Lymph Node Working Group Data Acquisition Project	3-Mar-03	Open	Treatment	15
SWOG	Melano ma	Phase III trial of high dose interferon alpha-2b versus cisplatin, vinblastine, DTIC plus IL-2 and interferon in patients with high risk melanoma	26-Jan-04	Open	Treatment	0
SWOG/ ECOG	Melano ma	A randomized, placebo-controlled phase III trial of yeast derived GM-CSF versus peptide vaccination versus GM-CSF plus peptide vaccination versus placebo in patients with no evidence of disease” after complete surgical resection of “locally advanced and/or stage IV melanoma	26-Jan-04	31-Oct-06	Treatment	1
ECOG/ CTSU	Melano ma	A Double-blind, Randomized, Placebo-Controlled Phase III Trial of Carboplatin, Paclitaxel and BAY 43-9006 versus Carboplatin, Paclitaxel and placebo in Patients with Unresectable Locally Advanced or Stage IV Melanoma	28-Nov-05	Open	Treatment	1
Dana Farber Cancer Institute	Prostate	Docetaxel (Taxotere®) plus 6-month Androgen Suppression and Radiation Therapy vs. 6-Month Androgen Suppression and Radiation Therapy for Patients with High-Risk Localized or Locally Advanced Prostate Cancer: A Randomized Controlled Trial	19-Dec-05	Open	Treatment	0
NMDP	Transpl ant	The Collection of Peripheral Blood Stem Cells Following Stimulation with Filgrastim	26-Sep-05	Open	Transplant	2
NMDP	Transpl ant	A Phase III Randomized Multi-center Trial Comparing G-CSF Mobilized Peripheral Blood Stem Cells with Marrow Transplantation From HLA Compatible Unrelated Donors.	26-Jan-04	Open	Transplant	0
UCI, Beckmen Laser Institute	Breast	Measurement of Breast Tissue Optical Properties (Device)	24-Jul-06	Open	Device / Screening	0
PI Initiated / Regional Cancer Center	Lung Cancer	Phase II Trial of Neoadjuvant Chemotherapy for the Treatment of IA-III A Non-Small Cell Lung Cancer	24-Jul-06	Open	Treatment	2
PI Initiated / Regional Cancer Center	Palliati ve Care	A Prospective Randomized Pilot Study to Evaluate the Screening Tools Used to Monitor in Palliative Care Patients	26-Jun-06	Open	Screening	0
AnorMED	Compas sionate Use	Compassionate Use Protocol for the Use of AMD3100 to Mobilize Peripheral Blood Stem Cells for Collection and Transplantation	24-Jul-06	Open	Treatment	2

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Sponsor (NCI/other)	Site	Title	Date Opened	Date Closed	Type	2006
ECOG	Breast Cancer	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial	23-Oct-06	Open	Treatment	0
ECOG	Renal Cell Carcinoma	A Randomized Double-Blind Phase III Trial of Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma	27-Nov-06	Open	Treatment	0
Accrual Totals:						133

K. Number of patients on clinical trials and % NCI-sponsored trials – provide in RFP format.

Sponsor (NCI only)	Site	Title	Date Opened	Date Closed	Type	2006	% Of Total
NSABP/ RTOG	Breast	A Randomized Phase III Study Of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) For Women With Stage 0, I, Or II Breast Cancer	25-Apr-05	Open	Treatment	3	2%
SWOG	Breast	A Phase III Trial of Continuous Schedule AC + G, versus Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer	31-Jan-05	Open	Treatment	1	1%
NSABP	Colorectal	A Phase III Clinical Trial Comparing Infusional 5-Fluorouracil (5-FU), Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks With Bevacizumab to the Same Regimen Without Bevacizumab for the Treatment of Patients With Resected Stages II And III Carcinoma of the Colon	22-Nov-04	6-Oct-06	Treatment	3	2%
UCSF	Rectal	Timing of Rectal Cancer Response to Chemoradiation	29-Aug-05	Open	Treatment	1	1%
ACOSOG	Colorectal	A Phase II Trial of Neoadjuvant Chemoradiation and Local Excision for uT2uN0 Rectal Cancer	24-Apr-06	Open	Treatment	0	0%
SWOG	Leukemia	Leukemia Centralized Reference Laboratories and Tissue Repositories, Ancillary	23-Dec-02	Open	Ancillary	0	0%
SWOG	Leukemia	Cytogenetic Studies in Leukemia Patients	23-Dec-02	Open	Ancillary	0	0%
SWOG	Lung	Lung Cancer Specimen Repository Protocol Ancillary Study	28-Jul-06	Open	Ancillary	0	0%

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SWOG/ ECOG	Lung	Phase III Chemoprevention Trial of Selenium in Resected NSCLC	22-Nov-04	Open	Treatment	0	0%
RTOG/ SWOG	Lung	Phase III Randomized Trial of Preoperative Chemotherapy versus Preoperative Concurrent Chemotherapy and Thoracic Radiotherapy Followed by Surgical Resection and Consolidation Chemotherapy in Favorable Prognosis Patients with Stage IIIA (N2) Non-Small Cell Lung Cancer	29-Aug-05	Open	Treatment	0	0%
UCSF	Melano ma	Sentinel Lymph Node Working Group Data Acquisition Project	3-Mar-03	Open	Treatment	15	11%
SWOG	Melano ma	Phase III trial of high dose interferon alpha-2b versus cisplatin, vinblastine, DTIC plus IL-2 and interferon in patients with high risk melanoma	26-Jan-04	Open	Treatment	0	0%
SWOG/ ECOG	Melano ma	A randomized, placebo-controlled phase III trial of yeast derived GM-CSF versus peptide vaccination versus GM-CSF plus peptide vaccination versus placebo in patients with no evidence of disease” after complete surgical resection of “locally advanced and/or stage IV melanoma	26-Jan-04	10/31/2 006	Treatment	1	1%
ECOG/ CTSU	Melano ma	A Double-blind, Randomized, Placebo-Controlled Phase III Trial of Carboplatin, Paclitaxel and BAY 43-9006 versus Carboplatin, Paclitaxel and placebo in Patients with Unresectable Locally Advanced or Stage IV Melanoma	28-Nov-05	Open	Treatment	1	1%
NMDP	Transpla nt	The Collection of Peripheral Blood Stem Cells Following Stimulation with Filgrastim	26-Sep-05	Open	Transplant	2	2%
NMDP	Transpla nt	A Phase III Randomized Multi-center Trial Comparing G-CSF Mobilized Peripheral Blood Stem Cells with Marrow Transplantation From HLA Compatible Unrelated Donors.	26-Jan-04	Open	Transplant	0	0%
UCI, Beckmen Laser Institute	Breast	Measurement of Breast Tissue Optical Properties (Device)	24-Jul-06	Open	Device / Screening	0	0%
ECOG	Breast Cancer	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: The TAILORx Trial	23-Oct-06	Open	Treatment	0	0%
ECOG	Renal Cell Carcino ma	A Randomized Double-Blind Phase III Trial of Adjuvant Sunitinib versus Sorafenib versus Placebo in Patients with Resected Renal Cell Carcinoma	27-Nov-06	Open	Treatment	0	0%
Accrual Totals:						27	20%

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L. Describe the focus of linkages with NCI-designated cancer centers or other academic research institutions.

SJO maintains links with several academic institutions, including City of Hope; the University of California, Irvine; the University of California, San Francisco; and Huntsman Cancer Center at the University of Utah. These relationships foster collaboration on shared research; increased research referrals for early phase trials and for trials not available at SJO; patient access to 2nd opinion services; physician interchange and participation in site-specific and genetic multidisciplinary conferences; and complex surgical procedures. A brief review of the components of care implicated in these linkages is below.

City of Hope

- Cancer genetics program link – enables SJO to develop the genetics testing/counseling program;
- COH serves as the biospecimen repository for genetics research;
- Continuing medical education—case conferences and didactic lectures;
- Research collaboration;
- Liver surgery expertise and related case conferences;
- 2nd opinion access, referral for selected BMT patients, and clinical education experts.

Huntsman Cancer Institute, University of Utah

- Genetics services;
- Research collaboration.

UC Irvine/Beckman Lab Research, Hiser Institute

- Research Collaboration;
- 2nd opinion access for patients.

UCSF

- Access to early Phase clinical trials;
- Other research collaboration.

The focus of collaboration with NCI-designated Comprehensive Cancer Centers is to establish collaborative relationships to offer increased access to clinical trials, resources and expertise to the SJO patient population. What we offer in return is a large patient population and an infrastructure to facilitate accrual to clinical trials to expedite achievement of study accrual targets, and access to Biospecimens, predominantly blood thus far, for genetics research and Biospecimen banking.

M. Describe the status of electronic medical records at the hospital and cancer center.

In 1999, SJHS and its Board made the decision to invest over \$150M in an Electronic Medical Record, supporting software, bio-medical devices, hardware and the network infrastructure to support these systems. The key goals for adopting an EMR were to obtain, manage, and use information to enhance and improve organizational performance in patient care, research, governance and management support services. This project was dubbed “Care ReDesign” (CRD for short). St. Joseph Hospital of Orange, one of the SJHS’s largest hospitals, receives an allocation of approximately 25% of CRD funding and the resources required to accomplish specific IT goals. In order to speed EMR installation and “go live” dates, SJHS formed a partnership with Perot System. Their objective was to develop an ISO certified data center. This certification encompasses the physical plant, policies and procedures, technical controls and systems security. An audited re-certification takes place every 6 months to ensure compliance.

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During that same year, SJO installed Meditech, the Electronic Medical Record and the associated ancillary and administrative modules. In 2000, a clinical design team was established to develop Data Standards and Best Practices, as well as to implement and integrate the Emergency Department's Clinical Documentation System. From 2000-2002, SJO implemented the PACs System, Ambulatory Medical Record, Pyxis, QS OB Clinical Record, Burlew On-Line Medical Library and a web-based Physician Portal. By 2005, these systems were well established and with a continued focus on patient care, the IT team implemented and integrated the Bed-Tracking System, PICIS OR, Case Management System and the Renal Center's Clinical System. In 2006, SJO completed several IT projects, including installing the KinetDx Cardiology Imaging System, Wireless Alaris Smart Pumps, and integrated the hospital's dietary System Cbord.

The physicians' web-based portal is continually being updated to provide clinician access to patient records, which include:

- Patient's Electronic Medical Record
- Ambulatory Electronic Medical Record
- Real-time access to lab, radiology, OR, respiratory, pharmacy and dietary
- Instant Updates on Emergency Room Visits
- Medical images (PACS), both radiology and cardiology
- Real-Time viewing of Fetal Monitoring
- PCP updates, Message Center and Referral Tracking
- Ability to correct on-line dictated documents
- Electronic Signature

A key emphasis of the hospital's overall strategy and mission is improving access to underserved communities in a continuum of care. The Community Clinics use the Coalition of Orange County Community Clinics Medical Records application and integrate results reporting from the hospital's EMR. SJO also provides a private Intranet that enables users to access a shared calendar of educational and wellness classes, medical library, comparison data and other information. The IT staff has solved several IT challenges related to serving patients in the four mobile clinics (Puente). At present Puente operates with three Verizon laptops used to register patients. All laptops interface with the hospital's Ccpro patient database system. Ccpro also enables Puente staff to interface with Quest Diagnostics systems/Unilab. Thus, providers and medical assistants can view patient lab results and order labs on line. Another success has been the ability to use SAM access accounts to remotely log on to the hospital's administrative workstation. Patients' Meditech appointment records are therefore available in real time in the mobile clinics; this helps manage daily patient flow.

In 2007, SJO will implement the Cancer Center's EMR, integrating it with the Meditech EMR, online clinical documentation, hospital-wide care plans and assessments, rollout of the Ambulatory Electronic Medical Record to affiliated physician groups, and Phase I implementation of a multi-dimensional clinical repository.

N. Describe the experience with biospecimen collection and banking.

The Cancer Center participates in two primary research initiatives that focus on biospecimen repositories. The first is a collaborative effort with City of Hope. The project banks biospecimens for genetic research purposes. To date, SJO has contributed 214 specimens to the COH study for molecular genetic studies of cancer patients and their relatives. SJO study contributions have led to two important findings to date – one, was contributing samples for Hispanic women for a study

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focused on hereditary breast cancer; and two, was a recent finding utilizing a new genetic testing methodology to verify the inheritance of a breast cancer DNA mutation.

SJO also participates in, and contributes biospecimens in support of NCI Cooperative Group trials. Historically, these are companion studies to therapeutic trials, and participation is predicated on first accruing patients to the companion trial. SJO prepares numerous specimens for banking and testing; including submitting confirmatory specimens for imaging research studies and hematopoietic progenitor cell (HPC) and bone marrow collection work with CHOC and NMDP (National Marrow Donor Program). SJO has collected over 400 HPC and bone marrow specimens and has been recognized as the nation's leading community hospital-based program within NMDP for transplant collections. The CHOC transplant processing lab evaluates, performs quality assurance measures, and then returns the tissue for distribution by NMDP. Established in 1992 by SJO, this program is often cited for best practices highlighting SJO staff's efficiency and completeness of work, related to collections and handling.

Two recent imaging studies (Naviscan's PET mammography study and the DOBI International Dynamic Optical Breast Imaging device study) required biopsy specimen submission for independent centralized laboratory confirmation of imaging results. Both trials were multi-center trials, with relatively short accrual periods. SJO accrued 36 patients to the PET study and 10 to the Optical Imaging device study. The Orange County Pathology Medical Group (OCPMG, who provides pathology services and leadership to SJO) supported these studies with procurement, evaluation and shipment processing of appropriate tissue to each study's respective centralized laboratory. In addition to these studies, SJO has 14 open studies requiring pathology slide submission as part of the research protocol. The pathology department plays an integral role in processing and ensuring proper slide submission.

The Orange County Pathology Medical Group (OCPMG) has provided pathology services and leadership to SJO for more than 25 years. The six pathologist members are board-certified in Anatomic and Clinical Pathology, as well as a subspecialty. Subspecialties include Hematopathology, Dermatopathology, Pediatric Pathology, and Cytopathology. OCPMG physicians examine and diagnose the hospital's surgical specimens and provide oversight and direction to the Pathology and Clinical Laboratory Departments. Leadership responsibilities include departmental operations oversight, staff and medical education, selection and evaluation of test methodologies and consulting with physicians regarding appropriate diagnostic tests. In addition, members of the group lecture at academic meetings, symposiums and at academic institutions, i.e. Stanford Medical School. They participate in NCI-funded research, are active members of NCI-sponsored cooperative groups and publish in various peer-reviewed journals. This laboratory is a California State Licensed Laboratory, certified by CLIA and accredited with Distinction by the College of American Pathology.

Within the practice, there are individual Directors for Dermatopathology, GI/Colorectal, Pediatric & Perinatal pathology, Transfusion services, Breast & Gynecologic, Hematopathology, Urologic, Pulmonary, Head & Neck pathology services, and Cytopathology. These pathology specialists are active members of the applicable Cancer Institute site-specific program teams and participate in research, case conferences, journal clubs, educational presentations and clinical outcomes evaluation and performance improvement efforts. The pathologists received their residency/fellowship training at institutions such as Stanford University, UC Irvine, Cedars-Sinai, and UCLA. One team member is a Stanford Medical School clinical instructor, one a Clinical Professor at UC Irvine; another holds a PhD in Cellular Biology. Lisa Kohorn, M.D. chairs the Department.

Dr. Sassoon, one of the Orange County Medical Group's pathologists was involved in lymphoma research, during his hematopathology fellowship at Cedars Sinai. His research, which involved tissue

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banking of all fresh lymphoma tissue for various studies, included PCR, immunohistochemistry and genetics (gene-rearrangement studies). The lymphoma fresh tissue bank collected specimens dating back over 20 years, providing tissue for studies performed. Dr. Sassoon published his research in two peer-reviewed journals (Publications List - Appendix D).

SJO pathologists assert their interest in developing unifying policies and procedures for NCI-supported biorepositories, whose tissue samples are used for basic, epidemiologic, translational and clinical research. The physicians are aware of the issues caused by the lack of common standard operating procedures, quality assurance/control measures, and importantly the lack of a common biospecimen repository database. Moreover, the need to develop consistent documentation, collection, processing, storage and retrieval guidelines in order to achieve voluntary conformance (needed in the community-hospital private practice setting) is a subject of interest to them. Finally, department leaders assert their capabilities to provide the appropriate level of staff and time to work on the First Generation Guidelines for NCI-supported Biorepositories (FGGS).