NCI Community Cancer Centers Program
Program Overview – Sanford USC Medical Center

A. Name and location of hospital

Sanford USD Medical Center
1305 W. 18th Street
Sioux Falls, SD 57117-5039

B. Name of cancer center: Sanford Cancer Center

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

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

The majority of the Sanford Cancer Center physicians and its medical leadership are employed members of Sanford Clinic, a 350+ physician multi-specialty group practice and an operating division of Sanford Health. The physicians represent a broad range of specialties and clinical experience enabling the delivery of comprehensive, multidisciplinary services to our patients. Sanford Health serves as the parent corporation for Sanford USD Medical Center, Sanford Clinic, Sanford Health Network, Sanford Health Plan and Sanford Health Foundation. This integrated structure supports the ability to organize, deliver and finance care in a comprehensive community cancer center.

Other physicians who are involved in the Sanford Cancer Center are in private practice and/or academic positions with historical, good working arrangements. In certain cases, contractual agreements exist with these physicians to provide key services.

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

Specialty	Total
Medical Oncology	6
Gynecologic Oncology	1
Pediatric Oncology	2
Radiation Oncology	4
Radiology	39
Nuclear Medicine	1
Thoracic Surgery	2
General Surgery	10
Neuro Surgery	2
Pathology	10
Palliative Care	1

Physicians providing services in the Sanford Cancer Center are credentialed through the Sanford Medical Staff credentialing process which provides a complete compliance and clinical privileging process. Where indicated for cooperative group clinical trial participation, specific credentialing arrangements are in place. Sanford Clinic has a Physician Covenant to which its physicians and the System adhere including support to patient care, quality, research and community outreach.

F. Describe multi-disciplinary care model

The Cancer Committee at SCC as established by the Medical Staff bylaws is a multi-disciplinary physician and staff committee, meets on a quarterly basis and consists of appointees who are actively interested in the diagnosis and treatment of cancer. Such individuals include but are not limited to surgery, medical and radiation oncology, pediatric oncology, gynecologic oncology, radiology, pathology, palliative care, gastroenterology, hospital administration, clinic administration, nursing, social services, cancer registry and quality improvement. Multidisciplinary cancer care is delivered effectively within the Sanford integrated health system model.

On September 4, 2003, the first patient was seen in the SCC Multi-Disciplinary Lung/Thoracic Clinic by clinic co-directors Michael Keppen, MD, a medical oncologist, and thoracic surgeon, John Vanderwoude, M.D. The Clinic provides for a coordinated plan of diagnosis and management for lung and esophageal cancer patients. It provides a single location for patients with thoracic tumors to receive multiple physician visits, imaging studies, multi-disciplinary case review and a coordinated treatment plan in a single one day visit. Most importantly, the outcomes for the patients are both efficient and most likely life-saving—patients referred to The Clinic received their first treatment on average within 16.2 days of the initial referral. This compares to reported industry averages of 86 to 126 days from presentation to treatment.

Key outcomes from the Lung/Thoracic Tumor Clinic model have included:

- Comprehensive team approach to determine the patient's best course of treatment
- Prospective evaluation by multi-specialty physicians with expertise in lung and other thoracic tumors
- Prompt and timely decision making regarding additional diagnostic studies required
- Access to cutting-edge treatment protocols including innovative cancer clinical trials

- Diagnostic evaluation using the most advanced imaging tools and techniques
- Review by palliative care specialists when disease has advanced

Support services are also an integral part of the multi-disciplinary approach to our cancer care. Specific support services provided to all patients as appropriate include:

- Clinical Research
- Education
- Genetic Testing and Counseling
- Hospice
- Mobile Services
- Nutritional Counseling
- Pain management
- Palliative Care
- Support Groups

The Sanford Breast Project is based on the lung/thoracic model to develop and provide a weekly multi-disciplinary breast conference for the management of breast cancer. The first breast conference was held on June 4, 2007 with 14 physicians and 20 non-physicians participating in the review of breast cancer cases. A key patient service goal for Sanford is to develop additional multidisciplinary cancer clinics and conferences for additional tumor sites.

G. Provide a brief overview of community demographics

The total population for Sanford's Market Area is 1,281,482 including a population of 217,500 in the Sioux Falls MSA. The race and gender of patients served at Sanford USDMC include:

Race Category	**FY2006**
White	94.2%
Black	1.3%
Native American	3.1%
Asian/Pacific	0.5%
Hispanic	1.0%
Gender	
Male	43.2%
Female	56.8%

Sioux Falls Community and State of South Dakota demographics:

	Sioux Falls Community	**South Dakota**
Race Category		
White	91.9%	88.7%
Black	1.8%	0.6%
Native American	2.1%	8.3%
Asian	1.2%	0.6%
Other	1.3%	0.5%
2 or More Races	1.7%	1.3%
Hispanic	2.5%	1.4%
Age Distribution (2000)		
Under 5 years	7.3%	6.8%
Under 18 years	25.2%	26.8%
65 years and over	11.1%	14.3%
Median Household Income	$49,762	$37,477

SMC serves a large rural and frontier population. The small rural communities served have "distress characteristics" relating to less than national average income, population density of less than ten per square mile and more than 20% of the population over age 65. These factors contribute to a disadvantaged population in terms of access to and availability of services. Sanford has 19 Critical Access Hospitals as part of the Health System that help serve the rural population.

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

The American Indian, the geographically isolated and poor populations in South Dakota are carrying a greater portion of the cancer burden than the general population and represent our greatest disparate populations. These groups are associated with high levels of cancer causing risk factors, low screening rates, and high late stage diagnosis and cancer mortality.

Caucasian women have a cancer incidence rate three times that of American Indian women, however, age-adjusted mortality rate is six-fold higher among American Indian. Only 39.4 percent of American Indian women ages 50 and older in South Dakota reported having had a clinical breast exam and mammogram within the preceding two years.

An increase in the number of American Indian women receiving recommended screenings and prompt diagnosis and treatment will translate into a lower mortality rate and is an area of high priority for our outreach efforts.

Access to quality cancer treatment is limited in South Dakota by lack of health insurance, cost of care, geographic location, travel time, transportation, education, cultural and language barriers. Sanford Health has identified these as major factors to address in reducing health disparities. Treatment and outreach programs are to be structured accordingly. Sanford serves its scattered population through 19 critical access hospitals, which serve as a safety net to ensure Medicare beneficiaries and other patients' access to health care in rural areas. In addition, the Sanford Cancer Center conducts education on the benefits of screening and clinical trials and utilizes its mobile mammography services, Partners in Prevention and other resources to reach its rural, elderly, poor, and minority patients.

Sanford's multi-prong approach to outreach programs includes:

- Ongoing public cancer education including the benefits of prevention, screening, early detection, treatment and research including encouraging enrollment in clinical trials targeting underserved and minority populations.
- Continuing education for staff regarding potential benefits to patients of underserved and minority populations.
- Communication and programming designed to target underserved and minority populations that informs, recruits and cares for members of these groups.

Specific examples of Sanford's commitment to addressing these issues include:

- SCC extensively utilizes the State sponsored All Women Count and Sister to Sister programs. These programs help form a community coalition of sorts in promoting screening for breast and cervical cancer. They provide a means for follow up for clinical trial participation and form relationships with patients in need of services without regard to payment source.

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- Sanford utilizes its extensive mobile mammography service to reach our rural disparate populations. Existing relationships with rural health facilities and the Sioux River Valley Community Health Center connect Sanford to low income and otherwise disadvantaged populations.
- Sanford's Partners in Prevention Program is a community-based model of outreach for addressing health care disparities. This comprehensive, mobile prevention program has developed an extensive network of regional rural community locations where it provides services. The program is also a "work site" based model which encourages people otherwise not likely to seek screening services to use them.
- Sanford's Multi-Disciplinary Lung/Thoracic Tumor Clinic provides for a coordinated plan of diagnosis and management for lung and other thoracic cancer patients. It provides a single location for patients with thoracic tumors to receive multiple physician visits, imaging studies, multi-disciplinary case review and a coordinated treatment plan in a single one day visit. These efficiencies reduce accessibility issues for minority and underserved populations, as well as the general population.
- Sanford Health has taken a leadership position with our own Sanford Health Plan to provide insurance coverage for cancer patients who are insured by the Sanford Health Plan and who are to be treated on clinical trials. Sanford Clinical Research Services and the Health Plan establish guidelines for each clinical trial protocol identifying what is covered under usual care and what is covered under research care and the method of determining each.
- Dr. Miroslaw Mazurczak chairs the South Dakota Comprehensive Cancer Coalition. This focus of this formal, ongoing statewide initiative is to address cancer health disparities across the entire state.
- Dr. Maria Bell, Co-Medical Director of the NCCCP Pilot Project will serve as a member of the National Cervical Task Force in a new comprehensive approach for development, evaluation and prioritization of clinical trials in gynecologic cancers.

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I. 2006 new cancer cases – provide in RFP format

Number of New Cancer Cases By Anatomic Cancer Site
Sanford Community Cancer Center

Disease Site ***(create separate rows as necessary)***	**Newly Registered Patients Jan-Dec 2005**	**Newly Registered Patients Jan-Nov 2006**
Head and Neck (lip, oral cavity, pharynx, eye, orbit)	20	21
Digestive System (esophagus, stomach, small intestine, colon, rectum, anus, liver, pancreas)	229	216
Respiratory (nasal/sinus, larynx, lung/bronchus)	169	167
Blood and Bone Marrow (leukemia, multiple myeloma, other)	39	39
Bone (Primary)	2	3
Connective Tissue	10	9
Melanoma	26	32
Other Skin Cancer	3	4
Breast Cancer (male and female)	209	169
Female Genital (cervix, ovary, other)	137	109
Male Genital (prostate, other)	155	138
Urinary System (kidney, bladder, other)	90	91
Brain & CNS (benign, malignant, other)	69	56
Endocrine System (thyroid, other)	58	28
Lymphatic System (NHL, Hodgkin's lymphoma)	37	37
Unknown Primary	17	22
Other/Ill-defined	8	3
TOTAL Analytic Cases:	1278	1144

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

Reportable Patients/Participation in Therapeutic Protocols By Anatomic Cancer Site
Sanford Community Cancer Center

Disease Site	2006
Head and Neck (lip, oral cavity, pharynx, eye, orbit)	0
Digestive System (esophagus, stomach, small intestine, colon, rectum, anus, liver, pancreas)	11
Respiratory (nasal/sinus, larynx, lung/bronchus)	3
Blood and Bone Marrow (leukemia, multiple myeloma, other)	8
Bone (Primary)	0
Connective Tissue	0
Melanoma	3
Other Skin Cancer	0
Breast Cancer (male and female)	14
Female Genital (cervix, ovary, other)	16
Male Genital (prostate, other)	8
Urinary System (kidney, bladder, other)	1
Brain & CNS (benign, malignant, other)	0
Endocrine System (thyroid, other)	1
Lymphatic System (NHL, Hodgkin's lymphoma)	4
Unknown Primary	0
Other/Ill-defined	42
TOTAL:	111

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

Summary of Cases Accrued to Clinical Trials at Sanford Cancer Center

Research Activity/Group	2006	2005	2004
American College of Surgeons Oncology Group	1		0
Cancer and Leukemia Group B Foundation (CALGB)	8	5	5
Children's Oncology Group *	6	6	18
Early Detection	0	2	1
Eastern Cooperative Oncology Group Foundation (ECOG)	9	16	21
Economics of Care	0		
Gynecologic Oncology Group (GOG)	8	6	18
National Surgical Adjuvant Breast & Bowel Project Foundation (NSABP)	10	12	7
National Cancer Institute Sponsored Cooperative Group Outreach Program (CGOP)	0		
National Cancer Institute Sponsored Community Cancer Oncology Program (CCOP) **	0 (80)	0 (128)	0 (113)
North Central Cancer Treatment Group (NCCIG)	29	86	48
Pharmaceutical Company Sponsored Research	18	30	3
Primary Prevention	15	1	10
Quality of Life	0	0	0
Radiation Therapy Oncology Group (RTOG)	0	0	1
Southwest Oncology Group (SWOG)	3	6	18
University-Related Research	0	0	0
Locally Developed, Peer-Reviewed Studies	0	0	0
Clinical Trials, Not Otherwise Specified	4	2	4
TOTAL	**111**	**172**	**154**
Annual Analytic Caseload	1248	1279	1197
Percent Accrued	8.89%	13.45%	12.87%
Percent on NCI Sponsored Trial	**6.41%**	**10.0%**	**9.4%**

*POG, CCG, IRSG, NWT are all combined under the children's Oncology Group (COG).

**CCOP Accruals are listed under individual research groups: ECOG, NCCTG, NSABP, SWOG, CTSU

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Information on Clinical Research Studies Open During 2006
Sanford Community Cancer Center

Sponsor (NCI/ Other)	Site	Title	Date Opened	Date Closed	Type (Behavioral, Therapeutic, Prevention, Observation)	2006 Accrual
ACOSOG	Digestive System	A Phase III Randomized Double-blind Study of Adjuvant STI571 (Gleevec™) Versus Placebo in Patients Following The Resection of Primary Gastro-Intestinal Stromal Tumor (GIST)	7/8/2003	4/18/2007	Therapeutic	1
CALGB	Digestive System	Phase III Intergroup Trial of Adjuvant Chemoradiation After Resection of Gastric or Gastroesophageal Adenocarcinoma	2/11/2003		Therapeutic	1
CALGB	Male Genital	Randomized Double-Blind, Placebo-Controlled Phase III Trial Comparing Docetaxel and Prednisone with and without Bevacizumab (IND #7921, NSC #704865) in Men with Hormone Refractory Prostate Cancer	6/17/2005		Therapeutic	7
IBCSG	Breast Cancer	Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer	10/14/2003		Therapeutic	1
IBCSG	Breast Cancer	Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women with Endocrine Responsive Breast Cancer	10/14/2003		Therapeutic	2
COG	Blood and Bone Marrow	Standard Risk B-Precursor Acute Lymphoblastic Leukemia	5/20/2005		Therapeutic	3
COG	Blood and Bone Marrow	Classification of Acute Lymphoblastic Leukemia	4/30/2004		Observation	2
COG	Other/Ill-defined	A COG Soft Tissue Sarcoma Biology and Banking Protocol	7/12/2002		Observation	1
ECOG	Blood and Bone Marrow	Phase II Pilot Study of Rituximab + CHOP in Patients with Newly Diagnosed Waldenstrom's Macroglobulinemia	7/13/2004	4/26/2007	Therapeutic	1
ECOG	Endocrine System	Phase II Study of Carboplatin Plus Paclitaxel Treatment of Advanced Thymoma or Thymic Carcinoma	3/20/2001	3/27/2007	Therapeutic	1
ECOG	Urinary System	Phase II Trial of Paclitaxel plus Carboplatin in Patients with Metastatic or Locally Advanced Collecting Duct Renal Cell Cancer	10/15/2004	8/30/2006	Therapeutic	1
ECOG	Blood and Bone Marrow	Phase III Randomized Trial of Autologous and Allogeneic Bone Marrow Transplantation vs Intensive Conventional Chemotherapy in Acute Lymphoblastic Leukemia in First Remission	5/11/1993	12/28/2006	Therapeutic	1
ECOG	Respiratory	Trial of Carboplatin, Paclitaxel, and Thoracic Radiotherapy with or without Thalidomide in Patients with Stage III NSCLC	2/29/2000	10/26/2006	Therapeutic	2

ECOG	Lymphatic System	Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent Non-Hodgkin's Lymphoma	1/13/2004		Therapeutic	1
ECOG	Melanoma	Placebo-Controlled Trial of Yeast-Derived GM CSF vs. Peptide Vaccination vs. GM CSF + Peptide Vaccination vs. Placebo in Patients with "No Evidence of Disease" After Complete Surgical Resection of Locally Advanced or Stage IV Melanoma	1/11/2000	10/31/2006	Therapeutic	1
Sponsor (NCI/ Other)	**Site**	**Title**	**Date Opened**	**Date Closed**	**Type (Behavioral, Therapeutic, Prevention, Observation)**	**2006 Accrual**
ECOG	Digestive System	Phase II Trial of Irinotecan/Docetaxel for Advanced Pancreatic Cancer with Randomization Between Irinotecan/Docetaxel and Irinotecan/Docetaxel Plus C225, a Monoclonal Antibody to the Epidermal Growth Factor Receptor (EGF-R)	9/16/2003	8/23/2006	Therapeutic	1
GOG	Female Genital	Prospective Study of Risk-reducing Salpingo-Oophorectomy and Longitudinal CA-125 Screening Among Women at Increased Genetic Risk of Ovarian Cancer	5/7/2003		Therapeutic	8
NCCTG	Digestive System	Randomized Phase III Trial of Oxaliplatin (OXAL) plus 5-FU / Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer	4/6/2004		Therapeutic	1
NCCTG	Respiratory	Phase I/II Study of Concurrent Chemotherapy and Escalating Doses of 3-D Conformal Radiotherapy (RT) Followed by Three Cycles of Chemotherapy for Unresectable NSCLC Using a New RT Paradigm	6/11/2002		Therapeutic	1
NCCTG	Other/Ill-defined	The Use of Valeriana Officinalis (Valerian) in Improving Sleep in Patients Undergoing Adjuvant Treatment for Cancer: A Phase III Randomized, Placebo-Controlled, Double-Blind Study	5/11/2004	3/9/2007	Therapeutic	3
NCCTG	Other/Ill-defined	Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Creatine for Cancer-Associated Weight Loss and Anorexia	1/21/2005		Therapeutic	2
NCCTG	Breast Cancer	Phase II Trial of Weekly Irinotecan and Docetaxel in Refractory Metastatic Breast Cancer	6/8/2004	11/3/2006	Therapeutic	1
NCCTG	Breast Cancer	Phase II Study of Capecitabine in Combination with Vinorelbine and Trastuzumab for the Second-Line Treatment of HER2+ Metastatic Breast Cancer	3/18/2005		Therapeutic	1
NCCTG	Digestive System	Phase II Study of Bevacizumab, Gemcitabine, Oxaliplatin in Patients with Metastatic Pancreatic Cancer	8/19/2005	5/19/2006	Therapeutic	1
NCCTG	Other/Ill-defined	The Use of American Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double blind, Dose-Finding, Placebo-Controlled Study	11/18/2005	7/5/2006	Therapeutic	9

NCCTG	Other/Ill-defined	Randomized, Controlled, Open-Label Trial of Empiric Prophylactic vs. Delayed Use of Zoledronic Acid for Prevention of Bone Loss in Postmenopausal Women with Breast Cancer Initiating Therapy with Letrozole after Tamoxifen	3/18/2005	3/31/2006	Therapeutic	9
NCCTG	Melanoma	Phase II Trial of Bevacizumab, Carboplatin and Paclitaxel (BCP) in Patients with Stage IV Melanoma	3/17/2006	11/3/2006	Therapeutic	1
NCIC CTG	Breast Cancer	Double Blind Randomization to Letrozole or Placebo for Women Previously Diagnosed with Primary Breast Cancer Completing Five Years of Adjuvant Aromatase Inhibitor Either as Initial Therapy or After Tamoxifen (Including Those in the MA.17 Study)	9/9/1997		Therapeutic	1
NSABP	Breast Cancer	Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy	3/11/2003	6/15/2006	Therapeutic	1
Sponsor (NCI/ Other)	**Site**	**Title**	**Date Opened**	**Date Closed**	**Type (Behavioral, Therapeutic, Prevention, Observation)**	**2006 Accrual**
NSABP	Breast Cancer	Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-FU, Epirubicin, and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) in Patients with Node-Negative Breast Cancer	5/11/2004		Therapeutic	1
NSABP	Breast Cancer	Phase III, Adjuvant Trial Comparing 3 Chemotherapy Regimens in Women with Node+ Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); DD Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel; DD AC Followed by DD Paclitaxel + Gemcitabine	11/19/2004	5/3/2007	Therapeutic	2
NSABP	Breast Cancer	Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer	4/15/2005		Therapeutic	3
NSABP	Digestive System	Phase III Clinical Trial Comparing Infusional 5-FU, Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks with Bevacizumab to the Same Regimen wtihout Bevacizumab for the Treatment of Patients with Resected Phase II and III Carcinoma of the Colon	10/15/2004	10/6/2006	Therapeutic	2
NSABP	Digestive System	Clinical Trial Comparing Preoperative RT and Capecitabine w/ or w/out OXAL w/ Preoperative RT and Continuous Intravenous Infusion (CVI) of 5-FU w/ or w/out OXAL in the Treatment of Patients w/ Operable Carcinoma of the Rectum	9/17/2004		Therapeutic	1
SWOG	Prostate	Prevention of Alzheimer's Disease with Vitamin E and Selenium, Phase III Ancillary to S0000 (SELECT)	6/11/2002		Prevention	10
SWOG	Prostate	Prevention of Cataract and Age-Related Macular Degeneration with Vitamin E and Selenium - SELECT Eye Endpoints (SEE), Phase III Ancillary to S0000-SELECT	8/10/2004		Prevention	5

SWOG	Melanoma	Phase III Trial of High Dose Interferon Alpha-2b vs. Cisplatin, Vinblastine, DTIC plus IL-2 and Interferon in Patients with High Risk Melanoma	12/12/2000		Therapeutic	1
SWOG	Blood and Bone Marrow	Phase IIb Study of Molecular Responses to Imatinib at Standard or Increased Doses, or Dasatinib (NSC-732517) for Previously Untreated Patients with Chronic Myelogenous Leukemia (CML) in Chronic Phase	2/18/2005	2/1/2007	Therapeutic	1
SWOG	Male Genital	Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer	5/14/1996		Therapeutic	1
AMGEN	Digestive System	PACCE - Amgen 20040249; BB-IND 8382; A Randomized, Open-label, Controlled, Clinical Trial of Chemotherapy and Bevacizumab With and Without Panitumumab in the First-line Treatment of Subjects With Metastatic Colorectal Cancer	7/1/2005	9/13/2006	Therapeutic	3
MCCRC	Other/Ill-defined	Phase III, Randomized Study of the Effects of Parenteral Iron, Oral Iron, or No Iron Supplementation on the Erythropoietic Response to Darbepoetin alfa for Cancer Patients with Chemotherapy-Associated Anemia	6/16/2006		Therapeutic	3
Genentech	Lymphatic System	LYMPHOCARE REGISTRY - The National LymphoCare Study: An observational study of treatment, outcomes and prognosis in patients with follicular non-Hodgkin's lymphoma	3/4/2004	3/7/2007	Observation	3
Sponsor (NCI/ Other)	**Site**	**Title**	**Date Opened**	**Date Closed**	**Type (Behavioral, Therapeutic, Prevention, Observation)**	**2006 Accrual**
Genentech	Breast Cancer	RegisHER - An Observational Cohort Study of Patients With HER2-Positive Metastatic Breast Cancer (Protocol H2757n)	4/17/2005	2/28/2006	Observation	1
Telik, Inc.	Female Genital	TELIK-3024 TLK286.3024 Phase 3 Randomized Study of TLK286(TelcytaTM)in Combination with Carboplatin (Paraplatin®) versus Liposomal Doxorubicin (Doxil®) as Second-Line Therapy in Platinum Refractory or Resistant Ovarian Cancer	8/2/2005	5/2/2006	Therapeutic	1
Sanofi-Aventis	Female Genital	TEACO - A Pilot Phase II Study Evaluating the Combination of Oxaliplatin and Docetaxel with Bevacizumab as First Line Therapy in Patients with FIGO Stage IB-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma (Protocol No.: PM_L_0239)	8/2/2005	5/4/2006	Therapeutic	7
Total						**111**

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

Sanford has an established oncology related relationship and linkage with the Mayo Clinic, Rochester, Minnesota, and its NCI Designated Cancer Center as part of its involvement with Mayo in the Community Clinical Oncology Program and North Central Cancer Treatment Group. This includes regular communication, consultation and referral associated with the clinical trial program, pathology, other research and advanced treatment only available at NCI designated cancer center locations.

During the last year, through a generous donation by Mr. T. Denny Sanford, a Pediatric Collaboration Program was formalized and funded between Sanford and Mayo Clinic involving pediatric education and research including an annual symposium, student/resident experience and a research grant program with co-principle investigator requirements by both institutions.

The Sanford Gynecologic Oncology Group program operates as a satellite of the Washington University (St. Louis, Missouri) Comprehensive Cancer Center GOG research base.

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

EpicCare® is the electronic medical record system at Sanford and represents a $50 million dollar investment. The first phase of the inpatient EMR (named DocZ) went live in November 2006. Phase II has a launch date of June 11, 2007. Complete implementation is expected by the end of 2009 or early 2010 for Sanford USD Medical Center. DocZ will link all Sanford entities together on a single platform. This will allow any system hospital, clinic, physician, lab, or other site to document and review patient information from a single source.

The implementation of the ambulatory EMR for EpicCare began December 2005 and is well underway in the primary care practices of Sanford Clinic. All primary care practices will have EMR implemented by July 2008. Specialty care practice implementation will follow primary care.

DocZ supplements its general capabilities with built-in specialty content and with modules that provide specialized workflow tools integrated with the core clinical system. An Oncology specific module will be implemented allowing for patient-specific treatment plans, treatment plan templates (protocols), dosage calculations, clinical alerts, flowsheets, treatment episode review, and diagnosis staging.

N. Describe the experience with biospecimen collection and banking

The Sanford USD Medical Center/LCM Pathology Histology Laboratory is a joint venture between the two named entities that is staffed by ten board certified pathologists and processes over 37,000 surgical pathology cases a year. The caseload includes over 10,000 Sanford USD Medical Center cases and over 27,000 reference cases from hospitals and clinics located in South Dakota, southwest Minnesota, northwest Iowa and northeast Nebraska. Forty to fifty renal biopsies per year are forwarded to the Mayo Clinic in Minnesota; otherwise all of the remaining tissues are processed in the lab using routine formalin fixation and tissue processing. Following pathologic examination and diagnosis, tissue blocks and microscope slides are stored indefinitely, allowing for future reviews of all cases as well as performance of additional immunohistochemical stains and other ancillary studies as needed for patient care. The histology laboratory performs 12,000 immunohistochemical stains and 2,500 frozen sections a year and also procures fresh frozen tissue for genetic and nucleic acid studies,

special oncology studies and neuromuscular biopsies. The nerve and muscle biopsies are processed in house, with the exception of the electron microscopy, which is accomplished by the Sanford School of Medicine Electron Microscopy Lab, which is located in Health Science Center on the Sanford USD Medical Center campus.

Over 81,000 cytology cases are processed and signed out yearly. This number includes 77,000 cervical cytologies, 58% of which are Thin Layer specimens, 2,100 body fluid cytologies, 900 fine needle aspirate specimens, and 1,000 pulmonary cytologies. These specimens are all processed and stored in house. Approximately 200 hundred autopsies are performed yearly. This number includes forensic cases (50%), hospital cases (15%) and reference cases (35%).

The hospital Pathology Department also serves as the Department of Laboratory Medicine for the Sanford School of Medicine of the University of South Dakota. The hospital and medical school also support the USD Pathology Residency program, with six residents at present.

The Sanford USD Medical Center Laboratory is a full service, high complexity laboratory licensed by CLIA and accredited by the College of American Pathologists. The clinical laboratory serves inpatients, outpatients and non-patients (referral specimens) of all ages and all levels of acuity in a four-state area, including South Dakota, Minnesota, Iowa and Nebraska. The clinical laboratory performs approximately 3.6 million reportable tests per year. One half of this volume is reference testing, with the remaining one half split evenly between the health care systems hospital and clinic patients.

Current Biospecimen Banking Relationships – The Sanford USD Medical Center Laboratory has obtained, prepared and shipped tissue for limited research projects by Sanford Health physicians and Sanford School of Medicine faculty. The laboratory has also obtained, prepared and shipped tissues for specific oncology protocols, including NCCTG, ECOG, NSABP, COG, and GOG protocols. All current tissue-banking activities are accomplished on a case-to-case basis.

Sanford Tissue Bank Committee – A Tissue Bank Committee has been formed at Sanford to determine and implement the requirements for a Tissue Bank for research. The Committee has adopted and will use the First Generation Guidelines for NCI Supported Bio Repositories in establishing and administering the Tissue Bank. Members of this committee include the Laboratory Medicine Department Chair of the Sanford School of Medicine and Hospital Pathologist, Sanford Hospital Laboratory Director, Sanford Chief Compliance Officer, Sanford Hospital Chief Clinical Officer, Sanford Clinic Administrative Director of Clinical Research, Sanford Clinic Transplant Service physicians, Sanford Clinic Gynecology Oncologist, Sanford Blood Bank Manager and the University of South Dakota Chief Compliance Officer.

Important to the work of this committee is identifying infrastructure requirements as well as developing opportunities associated with Sanford serving the State's Native American population. A closer association amongst clinical and basic science researchers is also being promoted as well as the recognition of the importance and role of the Institutional Review Board (IRB).

The current three year schedule for the full development of the Sanford Tissue Bank includes determining procedures and receive IRB approval to complete process and pursue guideline requirements by June 2007; identify and establish appropriate storage facilities and arrangements by June 2008; and, have all cooperative agreements and all requirements in place for full functionality by June 2009.