# Southern California Cancer Research Program

# Kaiser Permanente **Research**



Advancing Science, Enhancing Lives



### **About the Cancer Research Program**

The Kaiser Permanente Southern California Cancer Research Program engages in innovative research across the continuum, spanning etiology and prevention, screening and detection, treatment and quality of care, and cancer survivorship.

Our integrated health system, which links primary and specialty care as well as ancillary services, provides a rich environment for scientific inquiry and a robust infrastructure to translate findings into practice. The program brings together researchers with diverse clinical and scientific expertise to examine a wide range of cancer types.

Through partnerships with federal funders and other collaborators, researchers ask and answer important health questions with real-world implications for Kaiser Permanente's members and the public at large.



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# The Kaiser Permanente Southern California Difference

The Cancer Research Program brings together diverse clinical and scientific expertise to break new ground in our understanding of cancer. We use that knowledge to improve prevention programs, screening, quality of care, and health outcomes for cancer survivors.

### Leveraging integrated care delivery

Kaiser Permanente's integrated model links care and health records, making it possible for research teams to ask and answer questions that will change our understanding of cancer. Connecting outpatient and inpatient care as well as pharmacies and laboratories, our model allows researchers to overcome barriers encountered in health systems where care and coverage are not integrated. Because primary care and specialty care are linked, we can track patient care from screening to treatment and beyond. This helps us gain a more complete picture of factors that influence health outcomes.





### A diverse and stable population

Kaiser Permanente is one of the nation's largest notfor-profit health plans. Southern California is the organization's largest region, with 3.6 million members who broadly represent the diversity of age, sex, and race/ethnicity in the California population. The size, diversity, and stability of the population permit the rapid accrual of a representative sample size. The stability of the population also facilitates longitudinal research.

### Accelerating research with EHRs

Researchers have the benefit of access to Kaiser Permanente Southern California's rich clinical data systems. This includes a system-wide electronic health record (EHR) that tracks the care members receive; an administrative information infrastructure that records all diagnoses and utilization (including pharmacy, laboratory, and procedures); and a Surveillance, Epidemiology, and End Results (SEER)-affiliated cancer registry, which the Southern California Region has maintained since 1988.

### Improving quality across the spectrum

Kaiser Permanente has a strong commitment to improving clinical quality across the continuum of prevention, screening, diagnosis, treatment, end-of-life care, and survivorship. Research is an integral part of our quality improvement program. Our cancer screening rates for breast, colorectal, and cervical cancer are among the highest in the country. Clinicians and researchers are working together on a program to significantly reduce colorectal cancer.





### Linking scientific and clinical expertise

The cancer research team includes investigators with expertise in behavioral science, epidemiology, pharmacoepidemiology, biostatistics, health services, and clinical care. Full-time researchers collaborate closely with practicing clinicians in hematology/oncology, urology, gynecologic oncology, radiation oncology, pathology, genetics, pharmacy, and surgery. Combining this diverse scientific and clinical expertise with a resource-rich environment creates an unparalleled opportunity to advance knowledge about cancer.

### **Expanding research using existing cohorts**

Investigators from Southern California have established sizable cohorts for research on cancer and other health conditions. The California Men's Health Study brings together health records and lifestyle survey data from a cohort of more than 80,000 male Kaiser Permanente members in Northern and Southern California. The Kaiser Permanente Southern California Children's Health Study includes a cohort of nearly 1 million children and adolescents. Other cohorts have been formed to support studies of prostate cancer, breast cancer, colorectal cancer, and obesity.

# Our Cancer Research Program

"Our goal is to create unparalleled cancer outcomes by combining evidence-based medicine with coordinated care, systems engineering, and an aligned cancer research program whose results can be immediately incorporated into clinical care."



—Michael Kanter, MD, Medical Director of Quality and Clinical Analysis, Southern California Permanente Medical Group

### Integration of Research and Care

Research at Kaiser Permanente focuses on posing questions with real-world implications and translating findings from those studies into practice. Cancer researchers, practicing clinicians, and quality improvement teams collaborate to find answers that change care delivery and improve health.

Although quality improvement and research often operate in separate realms at other institutions, the leadership team at Kaiser Permanente Southern California has encouraged quality improvement and research teams to break out of those traditional silos.

"People focused on quality improvement have a grasp on the big questions of the day," said Michael Kanter, MD, Medical Director of Quality and Clinical Analysis, Southern California Permanente Medical Group.

"Researchers bring rigor to our evaluation process, so we better understand what works and what doesn't. By bringing expertise from both sides together, we can find answers that will help us to provide better care."

Researchers often look to clinicians to gain insights into potential new research topics and to develop questions that will lead to clinically relevant findings.

"Clinicians on the front lines understand where the evidence and quality gaps are," said Steven Jacobsen, MD, PhD, Senior Director of Research, Kaiser Permanente Southern California. "If clinicians are invested in research designed to improve quality, they will be more invested in making changes based on those research findings."

Clinicians who participate in research often do so because they want answers that will help them provide better care for their patients.

"As a physician, it's frustrating when a patient asks a question and we don't have a good, evidence-based answer," said Joanne Schottinger, MD, a practicing oncologist, the Assistant Medical Director of Clinical Analysis for the Southern California Permanente Medical Group, and the clinical leader for Kaiser Permanente's Care Management Institute's cancer program. "One of the exciting things about our program is that if we find an answer, we can share it with our colleagues and make it happen in practice."



### **Cancer Research and Quality Improvement Highlights**

### **Developing New Screening Guidelines for** Microscopic Hematuria

Clinicians and researchers from Kaiser Permanente Southern California found that microscopic hematuria<sup>1</sup>—blood found in the urine that can't be seen by the naked eye—doesn't necessarily indicate the presence of cancer. The findings suggest that tests routinely done on patients with this condition could be avoided. The research team also developed a screening tool to better diagnose certain types of cancer.

Based on the evidence gathered through this study, the Southern California Permanente Medical Group guidelines, which had been largely unchanged for two decades, were changed late in 2012. The study was published in Mayo Clinic Proceedings in early January 2013.

### **Using Natural Language Processing to Identify Lung Nodules in Health Records**

A new automated method using natural language processing developed by researchers at Kaiser Permanente Southern California accurately identified more than 90 percent of cases of lung nodules from free-text radiology notes in Kaiser Permanente's electronic health record.2

The study contributed to the creation of a new "safety net" program for Kaiser Permanente Southern California. The program identifies patients with lung nodules and reminds physicians to follow up with CT scans when appropriate.

Researchers, pulmonologists, radiologists, and the clinical operations staff collaborated to develop the safety net program and to modify regional guidelines for lung nodule management. The same group will work together to evaluate and improve the safety net.

<sup>1</sup> Loo RK, Lieberman SF, Slezak JM, Landa HM, Mariani AJ, Nicolaisen G, Aspera AM, Jacobsen SJ. Stratifying risk of urinary tract malignant tumors in patients with asymptomatic microscopic hematuria. Mayo Clin Proc. 2013; . 88:129-38

<sup>2</sup> Danforth KN, Early MI, Ngan S, Kosco AE, Zheng C, Gould MK. Automated identification of patients with pulmonary nodules in an integrated health system using administrative health plan data, radiology reports, and natural language processing. J Thorac Oncol. 2012;7:1257-1262.

# **Evaluating Prostate Cancer Quality Improvement Efforts**

Kaiser Permanente Southern California has quality improvement programs across the spectrum of care for prostate cancer. Researchers have played a critical role in the success of the program, bringing an unbiased and disciplined perspective to the evaluation process and building credibility for the program. Programs address a range of health concerns, including:

- · age-appropriate screening to prevent over-diagnosis,
- a safety net to ensure followup for men who have an abnormal PSA,
- an improved dosing regimen for Lupron (hormonal therapy) based on serum testosterone measurement,
- a program to evaluate the quality and outcomes of robotic technology,
- a program to prevent osteoporosis fractures for men treated with hormonal therapy, and
- a prospective registry capturing patient-reported outcomes and quality of life.

Results from many of these programs have been published in peer-reviewed literature. The program has also gained recognition internally, winning the Kaiser Permanente 2014 James A. Vohs Award for Quality.

### Aiming to Reduce Colorectal Cancer Mortality by 50% in Next Decade

The Southern California Permanente Medical Group has set a bold goal to cut in half the number of patients dying from colorectal cancer. From 2009 to 2011, the age- and sex-adjusted colorectal mortality rate was 13.8 per 100,000 person years. In 10 years, the group aims to reduce that to 6.9 per 100,000 person years.

Not many organizations are in a position to set this kind of goal for long-term survivorship. We have already laid much of the groundwork through successful quality improvement programs that have dramatically increased screening rates and improved quality of care.

Researchers will implement and evaluate a myriad of new and ongoing improvement efforts. Proposed programs include expanded screening programs for people at higher risk for aggressive colorectal cancer, clinical trials for the prevention of colorectal cancer, and lifestyle interventions for prevention of colorectal cancer recurrence.



### **Extending Research Capabilities Through Multi-Site Collaborations**

### Cancer Research Network (CRN)

Kaiser Permanente Southern California has been a member of the National Cancer Institute (NCI)-funded Cancer Research Network (CRN) since its inception in 1999. The CRN consists of 9 full-member and 6 affiliated non-profit health plan sites from across the United States. The goal of the network is to promote and facilitate research among scientists within and outside of the CRN to take advantage of the health systems' unique resources, including comprehensive clinical data systems and defined member populations. Scientists from the Department of Research & Evaluation have served as principal investigators and co-investigators on numerous CRN studies examining topics across the cancer research continuum, from disease etiology to end-of-life. Kaiser Permanente Southern California has shared comprehensive health information from its electronic data sources; chart reviews; and surveys of patients, providers, and administrators with researchers from other CRN health plans and collaborating academic institutions.

### Population-based Research Optimizing **Screening Through Personalized Regimens** (PROSPR)

The scientific goal of the NCI-funded PROSPR network is to support research that will advance understanding of how to improve the screening processes for breast, colon, and cervical cancer, from recruitment of patients through screening, diagnosis, and referral for treatment. It consists of 7 PROSPR Research Centers (PRCs), the Statistical Coordinating Center (SCC), and the NCI. There are 3 breast cancer PRCs, 1 cervical cancer PRC, and 3 colorectal cancer PRCs.

The Kaiser Permanente PRC is studying the screening process for colorectal cancer. It includes scientists from Kaiser Permanente Northern and Southern California, University of Pennsylvania, Memorial Sloan Kettering Cancer Center, and Erasmus MC. To date, the Kaiser Permanente PRC has provided detailed screening information on more than 2.7 million members, with 1.4 million from Kaiser Permanente Southern California's diverse patient population.

### Center for Effectiveness and Safety Research (CESR)

This Kaiser Permanente research center is a network of more than 400 researchers, clinicians, data managers, and analysts from 7 regions throughout the Kaiser Permanente national program. CESR was founded in 2011 to conduct studies of the safety and comparative effectiveness of drugs, devices, biologics, and care delivery strategies. Kaiser Permanente has led and co-led cancer-related studies including those that examined the incidence, treatment and recurrence of DCIS; PSA and prostate cancer mortality; and the comparative effectiveness for ACEI and ARB use in Stage IIIB/IV non-small-cell lung cancer.

### **PCORnet: The National Patient-Centered** Clinical Research Network and the PORTAL Network

The Patient-Centered Outcomes Research Institute (PCORI) was created to fund comparative clinical effectiveness research (CER) that will provide needed evidence to help patients and their caregivers make better-informed decisions. To facilitate more efficient CER, PCORI is developing PCORnet, a network that includes 11 Clinical Data Research Networks (CDRNs) and 18 Patient-Powered Research Networks (PPRNs). The Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) CDRN includes health systems that provide care for nearly 11 million people. It will create 3 cohorts, 2 of which are relevant to cancer research. Kaiser Permanente Southern California is leading development of the obesity cohort including over 3 million people and participating in development of a cohort that will include almost 12,000 patients with colorectal cancer.

# Southern California Regional Overview

As an integrated health care system,

Kaiser Permanente Southern California provides
an ideal environment for population-based
epidemiologic, clinical, and health services research.

The health plan's population includes more than 3.6 million Southern California residents who represent 200 different ethnicities and speak more than 120 different languages. Facilities include hospitals and medical offices, all linked by an information infrastructure that supports both clinical practice and business needs. Health information from this infrastructure can be leveraged for research purposes.

More than 90 percent of members remain in the health plan after one year; more than three-quarters remain after 3 years. As compared with the 2010 California census, membership is strikingly similar in terms of age, sex, and race.

### Map of Kaiser Permanente Southern California Region



Hospitals (diamonds), medical office buildings (circles), and other facilities (triangles).

# Kaiser Permanente Southern California at a Glance

Medical Centers (Hospitals)	14
Medical Offices	209
Physicians	6,000*
Nurses	20,000
Total Staff	61,000
Births per year	35,000

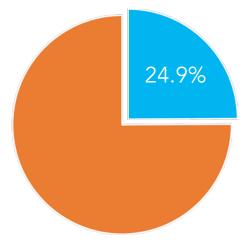
<sup>\*</sup>Includes active partners and associates.

# Demographic characteristics of the Kaiser Permanente Southern California membership on January 1, 2014, compared with the California census population

	Membership Number	Membership %	2010 CA Census %
Total population	3,633,210	100.0	100.0
Sex:			
Male	1,758,014	48.4	50.1
Female	1,875,196	51.6	49.9
Age:			
Under 5 years	198,338	5.5	7.4
5–9 years	226,419	6.2	6.7
10–14 years	247,228	6.8	7.0
15–19 years	274,356	7.6	7.3
20–24 years	272,669	7.5	7.2
25–34 years	462,737	12.7	14.5
35–44 years	474,588	13.1	14.1
45–54 years	509,980	14.0	14.1
55–59 years	250,822	6.9	5.7
60–64 years	212,868	5.9	4.7
65–74 years	310,010	8.5	5.9
75–84 years	144,678	4.0	3.7
85 years and over	48,517	1.3	1.6
Race:			
One race	3,562,161	98.0	96.2
White	2,159,528	59.4	62.7
Black or African American	398,859	11.0	6.1
American Indian or Alaska Native	24,258	0.7	0.8
Asian/Pacific Islander	471,941	13.0	12.9
Other race	507,574	14.0	13.8
Two or more races	71,049	2.0	3.8
Hispanic or Latino (of any race)	1,497,079	41.2	37.0

# % of cancer patients in Southern California cared for by Kaiser Permanente Southern California

	KPSC Members	Southern California Residents	% KPSC
Prostate	2,577	12,036	21.4%
Lung and Bronchus	1,309	8,778	14.9%
Breast	3,296	14,074	23.4%
Colorectal	1,396	8,131	17.2%
All Cancer Sites	17,487	70,182	24.9%

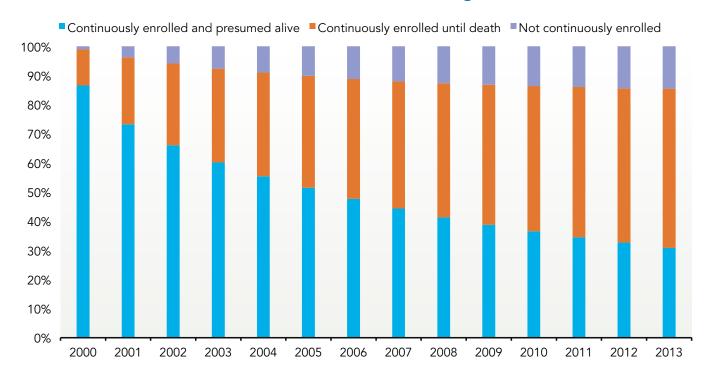


Note: Southern California defined by counties served by Kaiser Permanente Southern California Source: California Cancer Registry, cancer-rates.info/ca/index.php; KPSC Cancer Registry

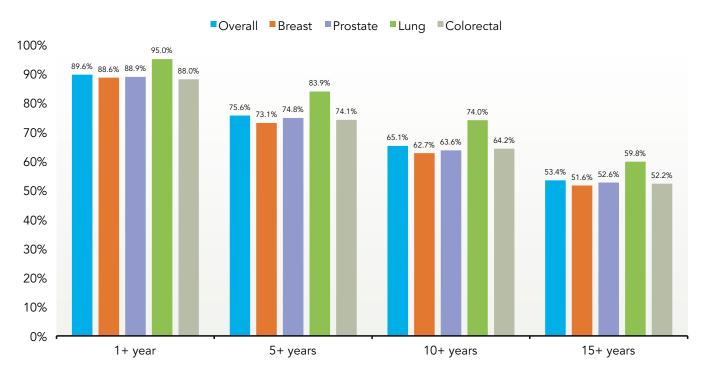
### Kaiser Permanente Southern California: New Cancer Cases 2013

Males		
Prostate	2,115	26%
Melanoma of the Skin	953	12%
Colorectum	783	10%
Lung and Bronchus	608	7%
Urinary Bladder	467	6%
Non-Hodgkin Lymphoma	413	5%
Kidney and Renal Pelvis	340	4%
Oral Cavity and Pharynx	298	4%
Leukemia	261	3%
Pancreas	187	2%
Thyroid	138	2%
Liver and Intrahepatic Bile Duc	t 114	1%
Other Cancers	1,494	18%
All Sites	8,171	100%

### KPSC continuous enrollment status after cancer diagnosis in 2000, all cancers



### KPSC length of continuous enrollment prior to cancer diagnosis in 2012



# Research in Kaiser Permanente Southern California

The Cancer Research Program is part of the Department of Research & Evaluation, based in Pasadena, California. The department leads and collaborates on research projects with clinicians and with partners from government, academia, and industry.

The Department of Research & Evaluation is the primary hub of research for Kaiser Permanente Southern California, supporting research by full-time faculty members as well as medical center-based clinician researchers.

Based in Pasadena, California, the department has grown exponentially in the past decade. In 2006, the department included 6 research scientists. Today, the faculty includes nearly 30 research scientists, a small group of post-doctoral research fellows, and a growing roster of associate investigators who are practicing clinicians.

The growth of the department began after Steven Jacobsen, MD, PhD, a nationally recognized chronic disease epidemiologist, was hired as scientific director. He soon recruited Sac Carreathers, an experienced research administrator, to help grow the research program.

In 2005, the department included about 64 people. Today, there are approximately 260 people at our Pasadena offices and nearly 100 others at medical centers and other Southern California locations. They include research scientists, biostatisticians, programmers, research support staff, research finance staff, information technology specialists, and administrative support staff.

The research program emphasizes translational research studies that have the potential to improve clinical quality and health care affordability. Faculty members focus primarily on externally funded public domain research.

### Research files

The medical record number serves as a unique identifier linking all medical encounters for each Kaiser Permanente member. Care received in the outpatient, inpatient, and emergency settings is documented in the electronic medical record and captured in research databases. Care received outside the Kaiser Permanente Southern California system is captured through claims information. The files are updated in near real-time.

### Growth of Department of Research & Evaluation, 2005-2014\*

		2005	2014*
Leadership Team	Scientific Director	1	1
	Administrative Director	1	1
Scientific Team	Research Scientists	4	27
	Post-Doctoral Research Fellows	0	7
	Associate Investigators	8	10
Biostatistics & Database	Managers	3	6
Development	Biostatistics	4	23
	Programming & Database Development	3	28
Research Support	Regional Offices	3	66
	Medical Centers and Other Regional Facilities	2	13
Clinical Trials	Regional Offices	3	14
	Medical Centers and Other Regional Facilities	19	83
Research Finance	Finance	3	14
	Sponsored Programs Administration	5	15
Administrative Support		4	22
Information Technology		1	17
Operations		0	4
Research Communications		0	3
Total		64	354

<sup>\*</sup>As of 6/27/2014

### The following are examples of files that can be used for research:

- Membership: Includes demographic information such as name, sex, date of birth, race/ethnicity, home address, email address, and phone number.
- Diagnosis: Includes International Classification of Diseases, 9th revision (ICD-9) codes.
- Procedure: Includes ICD-9, Current Procedural Terminology (CPT), and Systematized Nomenclature of Medicine (SNOMED) codes.
- Laboratory: Includes laboratory orders and results as well as pathology reports and results.
- Pharmacy: Includes National Drug Codes (NDC) and Generic Product Identifier (GPI) codes. More than 95 percent of members have a drug benefit with minimal copayments.

- Mortality: Includes deaths from hospital and membership databases, as well as from state and national death files. Also includes cause of death.
- Birth: Includes pregnancy-related information such as gestational age, birth weight, and Apgar scores.
- Registries: Includes cancer and HIV registries containing information such as patient demographics, utilization, disease history, and risk factors.
- Radiology: Includes information on radiology utilization and transcription notes.
- Claims information: Includes information on emergency and outside services.
- Kaiser Permanente HealthConnect®: Includes structured text and clinical notes from patient encounters.

# Our Research Capabilities

The research team has expertise and experience in performing a vast array of cancer research studies, ranging from epidemiologic studies to survivorship and end-of-life studies.

### The organization's unique infrastructure allows the team to:

- Identify subjects with particular exposures or diagnoses through electronic medical records.
- Ascertain outcomes through health care utilization files.
- Validate diagnoses through medical record review.
- Estimate incidence rates based on identification of persons with new disease onset and the person-time denominator from the membership files.
- Evaluate the natural history and clinical course of disease through passive followup of cohorts that are assembled retrospectively or prospectively based on disease incidence or exposure.

- Minimize recall bias by utilizing information captured in the medical records prior to disease onset rather than relying on patient recall.
- Follow cohorts actively with a prospective assessment of outcomes (e.g., patient-reported outcomes, satisfaction, quality of life, etc.) by taking advantage of current patient contact information.
- Identify and screen potential subjects according to pre-specified eligibility criteria, minimizing effort in the field.
- Evaluate participation bias using background information for persons agreeing to participate in a study as well as those who do not.



### Research & Evaluation's capabilities span the entire process, from project inception through dissemination of findings. Capabilities include:

- · Determining the appropriate study design and analytic approach to answer the research question of interest.
- Developing study protocols independently or collaboratively.
- Expediting Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act (HIPAA) processes while ensuring human subjects protection.
- Developing standard documents to ensure quality and consistency. These may include:
  - Project Management Plan.
  - Risk Management Plan.
  - Data Management Plan.
  - Case Identification Algorithms.
  - Case review/Adjudication Standard Operating Procedure.
  - Statistical/Data Analysis Plan.
  - Scientific Review Committee Standard Operating Procedure.
- Assembling large cohorts of subjects rapidly.
- Studying special populations such as people who are immunocompromised or women who are pregnant.
- Developing case identification algorithms using diagnosis codes, laboratory tests, and medications to identify outcomes of interest (e.g., autoimmune, rheumatologic, endocrine, neurologic, etc.).
- Conducting medical record review using our electronic health record system, Kaiser Permanente HealthConnect®.

- Managing case review and adjudication processes, including assembling committees of physician specialists.
- Employing secure electronic data collection methods.
- Collecting patient-reported information through mailed questionnaires, phone surveys, and inperson interviews.
- Collecting clinical specimens for research.
- Performing analyses involving pre-specified outcomes of interest or general safety analyses.
- Coordinating an independent Scientific Review Committee.
- Preparing interim and final reports for regulatory agencies.
- Presenting results at scientific meetings and to national advisory groups.
- Publishing results in peer-reviewed journals.
- · Coordinating kick-off meetings, site visits, and monitoring visits.
- Coordinating regular conference calls, including scheduling meetings, and preparing agendas and minutes summarizing discussion, decisions, and action items.
- Working with international collaborators.
- Providing strong project management support, including managing resources, communicating proactively, reporting on progress, and tracking timelines.
- Ensuring all deliverables are high quality and completed according to the scope of work, within budget, and on time.

# Advancements Through Clinical Trials

Clinical trials programs in Kaiser Permanente Southern California provide patients with cancer access to a wide range of treatment options. Cancer clinical trials for adults span oncology, surgery, radiation, and gynecologic oncology. Kaiser Permanente Southern California offers a pediatric oncology clinical trial program and a bone marrow transplant program for adults and children. Investigators work both with cooperative networks and with industry funders.



Kaiser Permanente Southern California is often a top recruiter for clinical trials. In 2011 and 2012, the adult oncology program was named as a "Top-Accruing Affiliate Institution" by the Southwestern Oncology Group, or SWOG, a cooperative group with the National Cancer Institute.

### **Cancer Types Treated in Recent Kaiser Permanente** Southern California Studies

### **Medical Oncology**

- Breast
- DCIS
- Invasive Breast Cancer
  - Neoadjuvant Chemotherapy
  - Adjuvant Chemotherapy
  - Supportive Treatment
  - Metastatic
- Colorectal
  - Adjuvant
  - Metastatic
  - Prevention (recurrence)
- Head and Neck
- Hepatocellular
- Leukemia
- Lung
  - Non-Small Cell
- Lymphoma
- Myelodysplastic Syndrome
- Neuroendocrine
- Pancreatic/Biliary
  - Metastatic
- Prostate
  - Metastatic
  - Supportive Treatment
- Renal/Bladder
  - Adjuvant
  - Metastatic
- Expanded Access-Sarcoma

### Surgical, Radiation and Gynecologic Oncology

- Cervical
- Endometrial
- Ovarian
- Vulvar
- Rectal
- Glioblastoma
- Head and Neck
- Prostate

### **Pediatric**

- Acute Lymphoblastic Leukemia
- Acute Myeloid Leukemia
- Hepatoblastoma
- Neuroblastoma
- Lymphoma
- Sarcoma
- Rhabdomvosarcoma
- Osteosarcoma
- Ewing's
- Brain Tumor
- Rare Tumors
- Renal Tumors
- Retinoblastoma



# Recent Cancer-Related Grants

Researcher	Grant	<b>Funding Agency</b>	Grant Period*
Chao, Chun	Intensity of End-of-Life Care Among Adolescents and Young Adults with Cancer (CRN Pilot Study)	NIH-NCI	9/1/2013– 8/31/2014
	Prognostic Markers for HIV-Related Diffuse Large B Cell Lymphoma		
	Statins and Lymphoid Malignancy Risk in a Large Multi-Site Population Based Cohort		
	Genomewide Association Study of Prostate Cancer	NIH-NCI	7/1/2013– 6/30/2014
Cheetham, Craig	Cardiovascular and Prostatic Safety of Testosterone Therapy in Aging Males	NIH-NIA	7/1/2012– 6/30/2014
	Long-term Use of Antihypertensive Agents and Breast Cancer Risk	Kaiser Permanente Center for Effectiveness and Safety Research (CESR)	
Chien, Gary	Personal Patient Profile-Prostate: Testing and Implementation in Health Networks	NIH	7/1/2013– 6/30/2014
Cooper, Robert	COG AALL1131 - A Phase III Randomized Trial for Newly Diagnosed High Risk B-precursor Acute Lymphoblastic Leukemia (ALL) Testing Clofarabine (IND# 73789, NSC# 606869) in the Very High-Risk Stratum	Industry	4/1/2014– 3/31/2020
	AALL1122 (BMS ID CA180-372): A Phase 2 Multi-Center, Historically-Controlled Study of Dasatinib (IND# 66,971) Added to Standard Chemotherapy in Pediatric Patients with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL)	Industry	2/28/2015
	A Phase II Pilot Trial of Bortezomib (PS-341, Velcade, IND# 58,443) in Combination with Intensive Re-Induction Therapy for Children with Relapsed Acute Lymphoblastic Leukemia (ALL) and Lymphoblastic Lymphoma (LL) - COG AALL07P1	Private	10/31/2014
	Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (ALL) COG AALL0932	Federal	2/28/2017

Project roles vary; roles include principal investigator, site principal investigator, and co-investigators.

Researcher	Grant	<b>Funding Agency</b>	Grant Period*
Danforth, Kim	Urinary Diversion Among Bladder Cancer Survivors: Cost, Complications, and Quality of Life (QOL)	NIH-NCI	7/1/2012– 6/30/2017
	Assessing Treatment Patterns and Quality Gaps in Non-Muscle Invasive Bladder Cancer Care	Kaiser Permanente Southern California Internal funding	10/1/2013– 9/30/2014
Girvigian, Michael	Randomized Phase II Trial of concurrent bevacizumab and Re- irradiation versus Bevacizumab alone a treatment for recurrent glioblastoma	NIH-NCI	10/14/2013– 9/15/2016
	Phase III trial on Concurrent and Adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON Intergroup trial	NIH-NCI	10/15/2013– 10/14/2016
	Phase II Double-Blinded placebo-Controlled study of Bevacizumab with or without AMG 386 in patients with recurrent Glioblastoma or Gliosarcoma.	NIH-NCI	10/15/2013– 10/14/2016
Gould,	Modeling lung cancer screening	Industry	
Michael	Improving decisions about evaluating pulmonary nodules for lung cancer	NIH-NCI	
	Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) Network	PCORI	4/1/2014– 9/30/2015
Hahn, Erin	A randomized trial to evaluate the impact of a radiation oncology-based survivorship care intervention	UCLA	
	Interregional utilization of low value interventions for cancer care	CESR	
Haque, Reina	Breast Outcome Disparities Following Breast Cancer Hormonal Therapy	California Breast Cancer Research Program	9/1/2013– 8/31/2016
	Sleep, Inflammation, and Depression Occurrence in Breast Cancer Survivors	NIH-NCI	10/1/2012– 10/1/2017
	CML: Outcomes of Chronic Myelogneous Leukemia and Adherence to Tyrosine Kinase Inhibitor Therapy	Industry	9/1/2013– 8/31/2016
	"OPATS": Outcomes of Prostate Cancer Androgen Therapy Study	NIH-NCI	4/1/2010– 7/1/2014
*Single date indica Project roles vary;	ates end date. roles include principal investigator, site principal investigator, and co-investigators.		

Researcher	Grant	Funding Agency	Grant Period*
Jacobsen, Steven J.	Computer-based Quality of Life Survey Outcomes of Prostate Cancer	Industry	9/15/2010– 8/31/2015
	Cardiovascular and Prostatic Safety of Testosterone Therapy in Aging Males	NIH-NIA	7/1/2012– 6/30/2014
Kawatkar, Aniket	Economic, Epidemiologic, and Clinical Burden Associated with Neutropenia and Febrile Neutropenia in Three Cancers.	Industry	2011–2014
Koh, Han	SWOG S1202, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early-Stage Breast Cancer.	NIH-NCI	7/16/2013– 7/15/2016
	A randomized, multicenter, double-blind Phase 3 study of PD-0332991 (Oral CDK 4/6 inhibitor) plus letrozole versus placebo plus letrozole for the treatment of postmenopausal women with ER (+), HER2 (-) breast cancer who have not received any prior systemic anti-cancer treatment for advanced disease	Industry	11/1/2013– 10/31/2015
	A Phase II, Double-Blind, Placebo Controlled, Randomized Study Evaluating the Safety and Efficacy of Carboplatin/Paclitaxel and Carboplatin/Paclitaxel/Bevacizumab with and without Gdc-0941 in Patients with Previously Untreated Advanced or Recurrent Non-Small Cell Lung Cancer [Protocol GO27912]	Industry	12/31/2018
	An open label, randomized (2:1) Phase 2b study of Dasatinib vs. Imatinib in patients with Chronic Phase Chronic Myeloid Leukemia who have not achieved an optimal response to 3 months of therapy with 400 mg Imatinib [BMS CA180-399]	Industry	1/31/2018
Polikoff, Jonathan	A Randomized Phase 2 Study of Cabozantinib (XL184) in Combination with Abiraterone in Chemotherapy Naïve Subjects with Bone-Metastatic Castration-Resistant Prostate Cancer	Industry	2/1/2014– 1/31/2017
	A Non-Interventional Follow-Up to the VELOUR study (multicentre international study of aflibercept versus placebo in combination with FOLFIRI for metastatic colorectal cancer)— Translational Research	Industry	10/1/2013– 9/30/2015
	A Phase III, Open-Label, Multicenter, Randomized Study To Investigate The Efficacy And Safety Of MPDL3280A (Anti-PD-L1 Antibody) Compared With Docetaxel In Patients With Non- Small Cell Lung Cancer After Platinum Failure	Industry	3/1/2014– 9/30/2016
*Single date indica Project roles vary:			

Researcher	Grant	Funding Agency	Grant Period*
Polikoff, Jonathan	An Open-Label, Multicenter, Randomized, Phase II Study to Investigate the Efficacy and Safety of MPDL3280A (Anti-PD-L1 Antibody) Compared with Docetaxel in Patients with Non-Small Cell Lung Cancer After Platinum Failure	Industry	7/1/2013– 6/30/2016
	A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with Locally Advanced or Metastatic Urothelial Bladder Cancer	Industry	5/1/2014– 4/30/2017
	NSABP Patient Registry and Biospecimen Profiling Repository	NIH-NCI	9/17/2013– 9/16/2016
	CIRB- NCCTG N1048: A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision	NIH-NCI	9/12/2013– 9/11/2016
	A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)	NIH-NCI	2/18/2014– 2/17/2017
Quinn, Virginia	Effectiveness of Screening Colonoscopy in Reducing Deaths from Colorectal Cancer	NIH-NCI	3/1/2013– 2/29/2016
	Establishing a Cohort to Study Cancers in Organ Transplant Recipients (CRN 2013 Developmental and Pilot Projects Program)	NIH-NCI	9/1/2013– 8/31/2014
	Diet and Lifestyle in a Prospective Study of Bladder Cancer Survivors	NIH-NCI	7/2/2014– 5/31/2019
	CRN4: Cancer Research Resources & Collaboration in Integrated Health Care	NIH-NCI	8/31/2017
	Comparative Effectiveness for ACEI and ARB use in Stage IIIB/IV NSCLC	CESR	1/1/13– 12/31/14
	Comparative Risks and Benefits of Gender Reassignment Therapies	PCORI	9/1/2013– 8/31/2016
Vasilev, Steven	A Randomized, Open-Label Study Comparing the Combination of YONDELIS and DOXIL/CAELYX With DOXIL/CAELYX Monotherapy for the Treatment of Advanced-Relapsed Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer	Industry	11/1/2013– 10/31/2016
Schottinger, Joanne	Optimizing colonoscopy and fecal immunochemical tests for community-based screening COLOFIT	NIH-NCI	9/26/2011– 8/31/2016
Young, Deborah *Single date indica	Trajectories of Physical Activity and Sedentary time in Adolescent/Young Women	NIH-NHLBI	
	rese and date.  Foles include principal investigator, site principal investigator, and co-investigators.		

### Cancer Research Team

### **Senior Investigators**



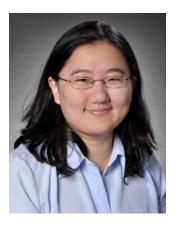
### Chun Chao, PhD, MS | Research Scientist II

Dr. Chun Chao is a cancer epidemiologist whose interests are primarily in lymphoid malignancies and adolescent and young adult cancer. Her research goals are to identify opportunities for cancer prevention, and to generate knowledge to guide care practices for cancer patients and survivors. Dr. Chao's ongoing projects examine correlates, barriers, and facilitators for HPV vaccine uptake for cervical cancer prevention; tumor and its microenvironment in predicting outcomes in patients with non-Hodgkin lymphoma; and the epidemiology and risk factors for developing severe chemotherapy-induced complications. Dr. Chao is an Adjunct Assistant Professor of Epidemiology at UCLA.



### Craig Cheetham, PharmD, MS | Research Scientist II

Dr. Craig Cheetham's research interests include drug and vaccine safety, medication adherence, and health services research. His work has focused on the safety of pharmaceutical products for pregnant women. Dr. Cheetham has also researched the cardiovascular risks associated with a variety of medications and drug classes. He is currently the co-principal investigator of a study evaluating the risk of exogenous testosterone on the development of prostate cancer in elderly males. Dr. Cheetham practiced hospital-based clinical pharmacy for nearly 20 years before coming to Kaiser Permanente. He recently joined the Department of Research & Evaluation after 10 years as a researcher within the Pharmacy Analytical Services Department.



Kim N. Danforth, ScD, MPH | Research Scientist I

Dr. Kim Danforth's primary interest is to use research to answer health questions with real-world significance. She has broad interests in health research and has studied a wide range of risk factors for bladder, ovarian, prostate, lung, and other cancers. These factors have included self-reported lifestyle factors, circulating markers, genetic variation, and administrative health data. She has conducted prospective, nested case-control, and cross-sectional studies in the context of several large cohort studies. Dr. Danforth is also involved in health services and outcomes-based research.



# Michael K. Gould, MD, MS | Director of Health Services and Implementation Research

Dr. Michael Gould uses observational and experimental research methods to compare the effectiveness of interventions for patients with lung cancer, venous thromboembolism, and acute and chronic respiratory disease. His other interests include the development and implementation of clinical practice guidelines and the use of computerized decision-support systems to improve the quality of care. Dr. Gould is a research associate professor of medicine at the University of Southern California's Keck School of Medicine.



### Reina Haque, PhD, MPH | Research Scientist II

Dr. Reina Haque is a senior cancer epidemiologist whose research interests include pharmacoepidemiology, cancer screening, and molecular markers for prognosis and cancer survivorship. She has led studies on breast, colorectal, and prostate cancer. Her studies have examined the incidence, treatment, recurrence, and pathology of cancer, as well as pharmaceutical use in cancer treatment. She is leading several survivorship projects, including common drug interactions in a large cohort of breast cancer survivors, cardiotoxicity following aromatase inhibitor use, and outcomes of chronic myelogenous leukemia by TKI drug adherence. Dr. Haque also serves as the scientific advisor to the Kaiser Permanente Southern California tumor registry.



### Aniket A. Kawatkar, PhD, MS | Research Scientist I

Dr. Aniket Kawatkar's research interests are in health inequity and disparities; health care and pharmaceutical utilization; and the associated economic, clinical, and humanistic outcomes. He uses established methods of econometrics, cost-effectiveness, conjoint analysis, and netbenefit analysis to evaluate interventions and treatments aimed at improving patient care in real-world clinical settings. Dr. Kawatkar's research focuses on comparative effectiveness, medication compliance and persistence, cost and expenditure data modeling, health-related quality-of-life issues, and health utility elicitation in chronic diseases. One of his current studies focuses on the economic, epidemiologic, and clinical burden of neutropenia and febrile neutropenia in breast cancer, lung cancer, and non-Hodgkin lymphoma.



### Corinna Koebnick, PhD, MSc | Research Scientist II

Dr. Corinna Koebnick's research interests include investigating the health consequences of obesity in children and young adults and improving health services for young people with obesity-related conditions. She has established a prospective cohort of approximately 1.9 million young adults in Northern and Southern California to investigate obesity, diabetes, and the metabolic syndrome as risk factors for cancer. Dr. Koebnick also leads the Kaiser Permanente Southern California Research Program on Genes, Environment, and Health. This program includes a large biobank resource that will link comprehensive electronic medical records, relevant behavioral and environmental factors, and information on genetic and non-genetic biomarkers from consenting Kaiser Permanente members. The program is designed to identify genetic and non-genetic factors involved in the pathogenesis of health conditions, as well as in the determination of treatment modalities that can improve care and disease outcomes.



### Steven J. Jacobsen, MD, PhD | Senior Director of Research

Dr. Steven J. Jacobsen is Senior Director of Research for Kaiser Permanente Southern California. A chronic disease epidemiologist by training, Dr. Jacobsen has a longstanding interest in men's urological health, cardiovascular diseases, developmental disorders, and vaccines. He has authored or co-authored more than 450 peerreviewed manuscripts, and has served on the editorial board of the American Journal of Epidemiology since 1997 and for Vaccine since 2011. He is a research professor of preventive medicine at the University of Southern California's Keck School of Medicine.



### Carly Parry, PhD, MSW | Research Scientist II

Dr. Carly Parry's research interests include health services research, cancer survivorship, processes and models of care, applied research and implementation, chronic illness, aging, the use of mixed methods, and psycho-oncology. Specific interests and expertise include coordination and quality of care delivery in transitional and follow-up care in chronic illness and cancer; survivorship care planning; metrics and measurement of quality in cancer care and care transitions; psychosocial outcomes and resilience; distress detection and management; and person-centered and team models of care.



### Virginia P. Quinn, PhD, MPH | Research Scientist II

Dr. Virginia Quinn is a behavioral health and health services researcher. Her focus includes the development and testing of interventions for changing diet, physical activity, smoking, and adherence to medications and medical treatment in diverse patient populations and families. Dr. Quinn is the Kaiser Permanente Southern California site principal investigator for the National Cancer Institute-funded Cancer Research Network. She is a co-investigator in the Kaiser Permanente PROSPR Research Center, studying the screening process for colorectal cancer. Her interests in cancer research include prevention, screening, quality of life, quality of care, and survivorship.



### Deborah Rohm Young, PhD, MBA | Director of Behavioral Research

Dr. Deborah Rohm Young's research interests include the conduct of physical activity intervention trials for adults and adolescents, based in primary care clinics and community settings. She also studies how physical inactivity and excess sedentary time are associated with cardiovascular risk and risk factors. She is interested in health behaviors during the transition from adolescence to young adulthood, and factors associated with maintaining physical activity, low sedentary time, and healthy weight status. Much of her work involves studying racial/ethnic minority groups to identify and reduce health disparities. Dr. Young is the lead scientist for development of the obesity cohort for the PCORI-funded Kaiser Permanente & Strategic Partners Patient Outcomes Research to Advance Learning (PORTAL) study.

### **Post Doctoral Research Fellows**

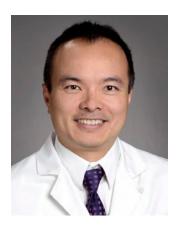


Erin Elizabeth Hahn, PhD, MPH | Post-Doctoral Research Fellow Dr. Erin Elizabeth Hahn is a health services researcher. Her primary interest is quality of care in oncology, focusing on clinical guideline implementation and delivery system issues. Dr. Hahn's work is a combination of qualitative and quantitative methods that explore variations in care, views and opinions of clinicians, and the association of patient-, clinician-, and system-level factors with health care utilization and outcomes. Her recent work focuses on overutilization issues in the delivery of post-treatment health services for breast cancer survivorship care.



Nirupa R. Ghai, PhD, MPH | Post-Doctoral Research Fellow Dr. Nirupa Ghai is a chronic disease epidemiologist. Her research interests include cancer epidemiology with a focus on health disparities, and prevention and screening. She is currently working on a colorectal cancer screening and prevention study. She is also interested in physical activity, obesity and medications/medical treatment in patient populations.

### **Clinical Collaborators**

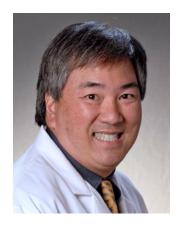


Gary W. Chien, MD | Urology, Los Angeles Medical Center Dr. Gary Chien is the Director of the Urology Residency Program and the Minimally Invasive Urology/Endourology Fellowship Program at the Kaiser Permanente Los Angeles Medical Center. His research interests include quality of life following prostatectomy, androgen ablation therapy for men with prostate cancer, and the safety and effectiveness of minimally invasive surgical procedures.



Neal M. Lonky, MD, MPH | Obstetrics-Gynecology, **Orange County Area** 

Dr. Neal Lonky practices obstetrics and gynecology at Kaiser Permanente Orange County. He has expertise in laparoscopic surgery, minimally invasive surgery, and management of lower genital tract disease. His research interests include cervical cancer screening, diagnosis, and prevention; comparative effectiveness of gynecological interventions; and women's health care policy and management.



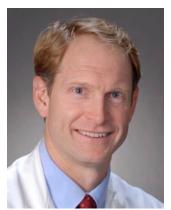
Ron Loo, MD | Urology, Downey Medical Center

Dr. Ron Loo is Chief of Urology at Kaiser Permanente Downey, Regional Chief of Urology for the Southern California Permanente Medical Group, and chair of the Kaiser Permanente Interregional Chiefs of Urology. He is also a faculty member at the Los Angeles Medical Center Urology Residency Program. His recent research has focused on asymptomatic microscopic hematuria and localized prostate cancer.



### Joanne Schottinger, MD | Hematology/Oncology, Panorama City Medical Center/Regional Offices

Dr. Joanne Schottinger is the Assistant Medical Director of Quality and Clinical Analysis for the Southern California Permanente Medical Group. She is a practicing oncologist, the physician lead for regional outreach and cancer clinical goals, and the clinical lead for Kaiser Permanente's Care Management Institute's cancer program. Her research interests include breast cancer, colorectal cancer, and prostate cancer. Dr. Schottinger is the site principal investigator for the Kaiser Permanente PROSPR Research Center studying the screening process for colorectal cancer.



### Stephen G. Williams, MD | Urology, Riverside Medical Center

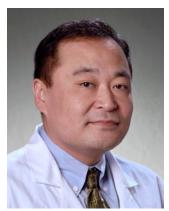
Dr. Stephen Williams is Chief of Urology at Kaiser Permanente Riverside. He has been a urologist with Kaiser Permanente Southern California since 2002, serving as one of our Regional Urologic Oncologists during that time. His primary clinical and research interests are in bladder cancer, and he treats many of the complex bladder cancer patients in the region. He recently served as the site principal investigator on a multicenter randomized controlled trial of bladder cancer treatment and is co-investigator on several ongoing bladder cancer studies.

### **Clinical Trials Investigators**



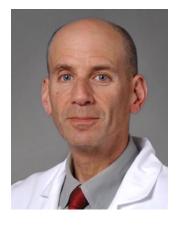
Robert Cooper, MD Hematology/Oncology, Los Angeles Medical Center

Dr. Robert Cooper leads the Kaiser Permanente Southern California Pediatric Clinical Trials Program, which oversees clinical trials for children and adolescents with cancer. He is also the Principal Investigator for the Children's Oncology Group, Kaiser Permanente Los Angeles Medical Center. His research interests include issues related to treatment and survivorship of cancer during childhood and adolescence as well as the young adult populations.



Han Koh, MD Hematology/Oncology, Downey Medical Center

Dr. Han Koh is a principal investigator for the Cancer Clinical Trials Access Program for Kaiser Permanente Southern California. He practices at Kaiser Permanente Downey. He leads clinical trials for a range of adult cancers, including pancreatic, prostate, and renal cancers, and non-Hodgkin lymphoma.



Jonathan Polikoff, MD Hematology/Oncology, San Diego Medical Center

Dr. Jonathan Polikoff is the Director of the Cancer Clinical Trials Access Program for Kaiser Permanente Southern California, which oversees oncology clinical trials for the prevention and treatment of cancer in adults. The program currently makes 25 to 30 trials available to Kaiser Permanente members who need treatment for a wide variety of malignancies; about three-quarters are with NCI-sponsored cooperative groups. This program was recognized by ASCO in 2008 with the Clinical Trial Participation Award and has been the highest-accruing SWOG affiliate for the last 2 years.



Michael R. Girvigian, MD Radiation Oncology, Los Angeles Medical Center

Dr. Michael Girvigian is the Assistant Chief for the Department of Radiation Oncology at the Kaiser Permanente Los Angeles Medical Center. He is also the principal investigator for Radiation Therapy Oncology Group clinical trials at Kaiser Permanente Southern California. Dr. Girvigian specializes in the management of central nervous system tumors of the brain and spine, as well as soft tissue tumors. He has been active in clinical research for many years.



Scott E. Lentz, MD Gynecologic Oncology, Los Angeles Medical Center

Dr. Scott Lentz is the Regional Gynecologic Oncology Director for Southern California Permanente Medical Group as well as Los Angeles Regional Services. For the past 9 years, he has been the principal investigator for Gynecologic Oncology Group Trials and the co-investigator for industry-sponsored clinical trials, including many practicechanging Phase II and Phase III gynecologic oncology trials. His clinical research interests include uterine sarcomas, novel approaches in minimally invasive surgery, and the history of colposcopy.



### Ricardo Tomas Spielberger, MD | Internal Medicine-Bone Marrow Transplant, Los Angeles Medical Center

Dr. Ricardo Spielberger is Director of Bone Marrow Transplantation for the Southern California Permanente Medical Group. A board-certified hematologist and medical oncologist with subspecialty training in stem cell transplantation, Dr. Spielberger joined Kaiser Permanente's bone marrow transplant team in 2000. His research interests include the use of hematopoietic cell transplantation for the treatment of hematologic malignancies, with emphasis in leukemias. He has also been involved in clinical trials focused on the use of new agents to reduce serious side effects following transplant and the management of opportunistic infections.



Steven Vasilev, MD, MBA Gynecologic Oncology, Los Angeles Medical Center

Dr. Steven Vasilev is Director of the Surgical and Radiation Oncology Clinical Trials Access Program, which conducts clinical trials at several Kaiser Permanente Southern California medical centers. He initiated our Gynecologic Oncology Group clinical trials program and oversaw its expansion as it grew to include surgical, radiation, chemotherapy, and biological trials. It now spans surgical, gynecologic, urologic, head and neck, and neurologic oncology departments.

# For more information • For more information about the Kaiser Permanente Southern California Cancer Research Program, please contact Virginia Quinn, PhD, at virginia.p.quinn@kp.org. • To learn more about research at Kaiser Permanente Southern California, visit www.kp-scalresearch.org.

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