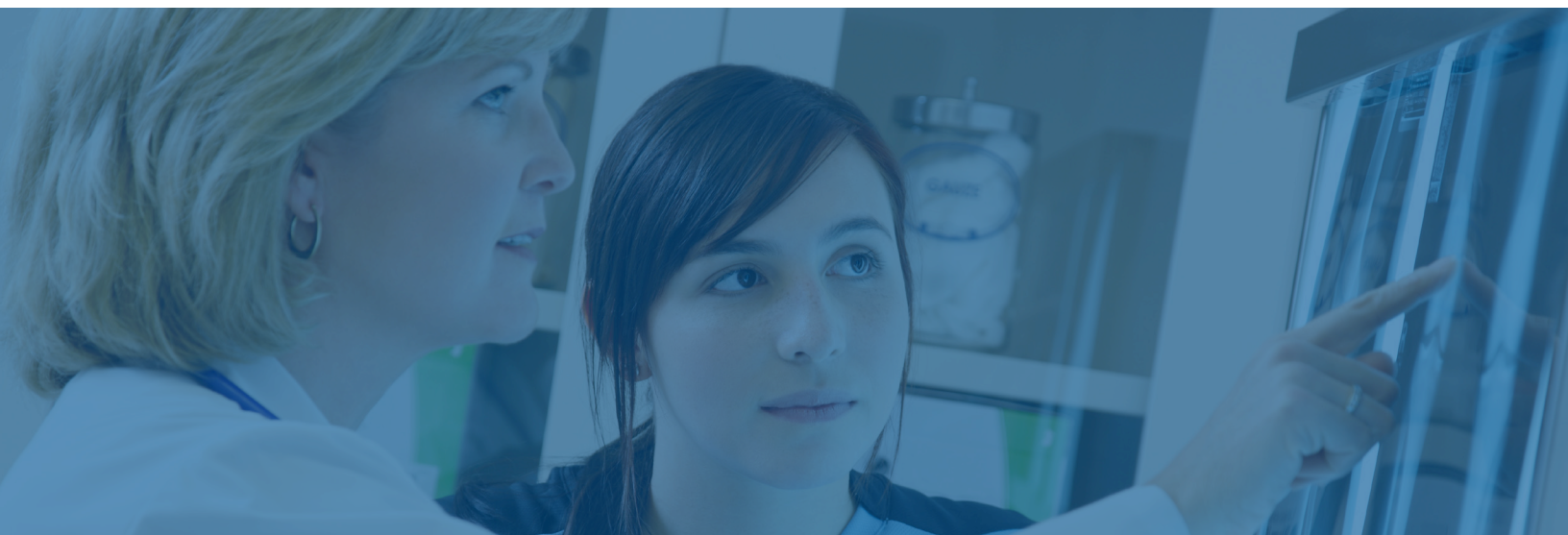


Kaiser Permanente Southern California | 2010 Annual Report





Vision

The Department of Research & Evaluation has an integral role in the success of Kaiser Permanente Southern California by conducting high-quality, innovative translational research that benefits the health of its members and the communities from which they come.



Mission

The mission of the Department of Research & Evaluation is to initiate and conduct high-quality, public-sector health services, epidemiologic, behavioral and clinical research that has a demonstrable positive impact on the health and well-being of Kaiser Permanente Southern California members and the general population.

Advancing Science, Enhancing Lives



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Steve Jacobsen, MD

Director's Message

Looking back at 2010, I am impressed by our progress. The Department of Research & Evaluation (R&E) continues to grow rapidly, more than tripling in size in the past five years. Research funding is on the rise, and our faculty are publishing findings in top scientific journals.

But what is truly inspiring is the research our team is producing. As varied as our research topics and methodologies are, there is an increasingly common thread—research that makes a difference in people's health, not in the distant future, but today.

Grant Funding

The grants we received in 2010 are great examples of our focus on translational research. The National Institutes of Health (NIH) awarded new grants, with R&E scientists as principal investigators, to search for answers to important clinical questions, such as:

- Do antidepressants in combination with tamoxifen, a common chemotherapy for breast cancer survivors, elevate the risk of breast cancer recurrence?
- How can clinicians intervene more effectively with chronic kidney disease to reduce racial and ethnic disparities in the progression to end stage renal disease?
- What are the health consequences of obesity, particularly extreme obesity, in children?

Our faculty members are building reputations as strong scientific partners. A number serve as site principal investigators for major collaborative networks. Our faculty have also secured industry funding to conduct research that can help us improve the safety and effectiveness of the treatments we offer our members.

Significant Publications

In 2010, scientists and physician researchers in Kaiser Permanente Southern California (KPSC) published more than 200 papers; more than 90 of these as first-author papers. Topics include diabetes, cancer, eye research, obesity, orthopedic care, vaccine safety, and more.

A number of these papers have generated media attention, accounting for more than a third of all the positive press KPSC received in 2010. One study that created quite a stir in the media focused on the health consequences of extreme obesity in children, making headlines in the national media via prominent outlets such as National Public Radio and *NBC Nightly News*.

Supporting Physician Research

Physicians in the Southern California Permanente Medical Group (SCPMG) offer unique insights into important clinical questions, given their clinical expertise in a unique integrated care setting. In 2010, we took a number of steps to increase support for physicians engaged in research, such as:

- Hiring an administrative assistant to support physicians with manuscript preparations.
- Providing one-on-one consultations on study design, biostatistical analysis, survey development, and other research issues.
- Partnering with residency programs to develop a joint research project involving residents from several Family Medicine programs.

The Department has also provided direct support for the strategic clinical research initiative led by Neal Lonky, MD, chair of the quality of care committee for the SCPMG Board of Directors. This has included building SmartSets to capture key data and interviewing patients to gather additional information.

New Scientists

With funding from the Garfield Memorial Fund, R&E recently recruited a new investigator, Jason Jones, PhD, MS, who will partner with a regional medical administrator to address high-impact questions in the hospital setting.

In 2010, R&E also recruited two post-doctoral fellows. Rulin Hechter, MD, PhD, focuses on vaccine safety and effectiveness. Kim Porter, PhD, MPH, studies prostate cancer.

I'd also like to acknowledge and thank Dan Strickland, PhD, MPSH, who retired in 2010 after eight years with R&E. Dr. Strickland played an important role, stepping in as Interim Director of Research in 2004 and 2005. In addition to conducting his own research, which ranged from cardiovascular disease to autoimmune disorders, he also offered consulting services to physicians interested in pursuing research projects. We are grateful for his many contributions and wish him well.

New Scientific Partnerships

In 2010, our Department joined forces with other Kaiser Permanente research institutes to develop a new center for trans-regional research. The Kaiser Permanente Center for Effectiveness and Safety research will make it easier for us to bring together our varied scientific interest and expertise to research important clinical questions across our member population.

Another new partnership is with the Los Angeles Basin Clinical and Translational Science Institute (LAB-CTSI), a consortium spearheaded by the University of Southern California. This will facilitate access to educational and core facilities there, as well as enhance the number and quality of Kaiser Permanente Southern California's collaborations with affiliated investigators in addressing important translational research questions.

Information Technology

In 2010, R&E set up a research data center exclusively for Kaiser Permanente Southern California, which provides greater flexibility and timeliness in responding to research questions for Kaiser Permanente. The data center allows much more efficient use of R&E's databases and supports collaboration through faster response to queries.

The IT team, along with our Web Committee, invested considerable energy in designing a new website, which was launched early in 2011. I invite you to visit the site at www.kp-scalresearch.org.

The following pages highlight examples of our achievements. Bear in mind that this is not an exhaustive report—our scientists and staff have accomplished much that is not detailed here, and I'd like to thank each of them for their contributions.

I hope you enjoy reading this report and learning more about the exciting research happening at KPSC.

Be well and thrive.



Steve Jacobsen, MD



Department of Research & Evaluation At-A-Glance

The Department of Research & Evaluation is the scientific research division of Kaiser Permanente Southern California, an integrated health care system serving 3.4 million members.

The Department consists of more than 200 team members, including research scientists, biostatisticians, programmers, research support, clinical trials staff, grant administrators, information technology personnel, administrative support, and others. Most team members are based in Pasadena, California. About 40 work in other areas of Southern California.

History

Research has been a part of Kaiser Permanente Southern California for nearly half a century. The first formal research department was established in 1963, with the founding of the Education & Research Department. Research became part of the Department of Clinical Services in 1982. The current Department of Research & Evaluation was founded in 1988.

Four Main Categories of Research

(1) Clinical | (2) Behavioral | (3) Epidemiological | (4) Health Services

Leadership

Director of Research Steven Jacobsen, MD, PhD joined R&E in 2006. In addition to conducting his own research in vaccine safety, men’s health, and cardiovascular health, Dr. Jacobsen leads the Department’s scientific team, which includes 18 full-time research scientists.

Director of Research Administration Sac Carreathers joined R&E in 2007. His responsibilities include oversight of seven business units: Biostatistics and Database Development; Clinical Trials; Research Support; Research Finance Office; Administrative Support; Research IT; and Research Operations.

People

The team has grown rapidly in the past five years, adding to the depth and breadth of scientific expertise. It is a diverse group, including many staff members who are multilingual. Languages spoken in addition to English include Spanish, Chinese, German, Korean, and Japanese.

Funding/Budget

Research is supported by government agencies, foundations, and other nonprofit entities.

	2010	2009
SCPMG Operations	\$ 6.0M	\$6.1M
Community Benefit	\$ 4.9M	\$4.3M
For Profit Entities	\$ 6.4M	\$6.0M
Federal/State/Local Agencies	\$10.5M	\$7.2M
Other Nonprofit Entities	\$ 0.2M	\$0.4M
Other Internal Funding	\$ 0.8M	\$0.2M
Total Funding:	\$28.8M	\$24.2M

2010 Accomplishments

Grants & Awards

R&E scientists maintained a strong track record in obtaining extramural funding, including major grants from the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

R&E had the following grant activity for 2010:

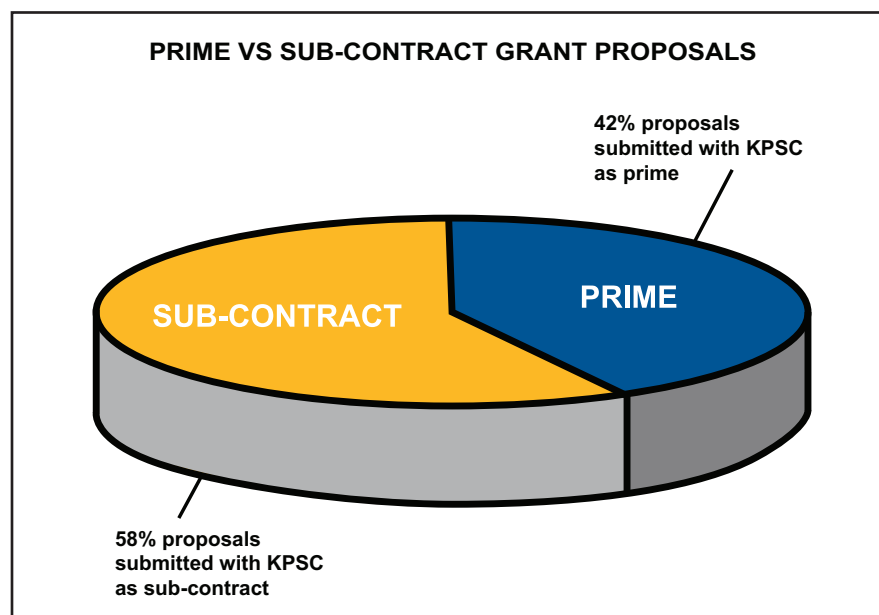
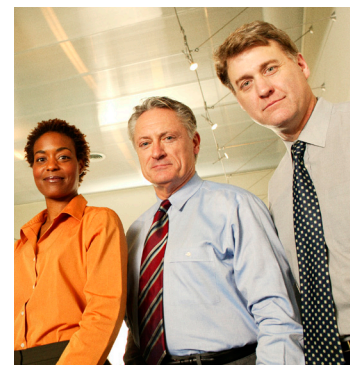
- 256 total grant and contract submissions,
- 127 new submissions,
- 124 non-competing renewals,
- 4 resubmissions, and
- 1 supplement to an existing grant.

Of the 256 submissions

- 158 have been awarded; 56 percent are new awards,
- 7 are not yet funded,
- 54 are under review,
- 36 no cost extensions were granted, and
- 1 was withdrawn.

For 2010, R&E had a **52.51 percent funding rate** based on the new proposals submitted.

R&E received a total of \$20.4 million in new grant awards in 2010. These grants will support ongoing research, new projects, and clinical trials over a period of years.



Kaiser Permanente Southern California was the prime grant recipient for 42 percent of proposals submitted in 2010.

Grants & Awards

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Grant Highlights

The following are just a few examples of new 2010 federal awards with R&E scientists serving as primary investigators:

- **Antidepressants and Breast Cancer Pharmacoeconomics:** Reina Haque, PhD is the principal investigator for a \$1.8 million grant from the NIH/National Cancer Institute to examine common drug interactions in a cohort of nearly 20,000 breast cancer survivors. The study will determine if combined use of certain antidepressants (including serotonin-specific reuptake inhibitors, or SSRIs) and tamoxifen elevate risk of breast cancer recurrence. Dr. Haque will be working with colleagues in Southern California Permanente Medical Group (SCPMG), Kaiser Permanente Northern California (KPNC), and Harvard Medical School.
- **Disparities in Progression to Renal Replacement Therapy:** Stephen Derose, MD, is the principal investigator for a NIH/National Institute of Diabetes and Digestive and Kidney (NIDDK)-funded retrospective cohort study among members of Kaiser Permanente Southern California to study the clinical determinants of end-stage renal disease. Chronic kidney disease is now recognized as a major public health problem, and rates of end-stage renal disease are particularly high among African Americans. The insights gained from this study will help guide clinical interventions to reduce racial/ethnic disparities and benefit patients with chronic kidney disease, regardless of race or ethnicity.
- **Childhood Obesity:** Corinna Koebrick, PhD, is the principal investigator for a NIH/ National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-funded study of childhood obesity involving more than 920,000 children. KPSC's large and diverse population offers a unique opportunity to look at the health consequences of obesity, particularly for children who are extremely obese. Potential health consequences of childhood obesity include cardiovascular risk factors such as hypertension and dyslipidemia, but also common conditions such as asthma, psoriasis, and functional digestive disorders.



R&E scientists also play a leading role in research conducted by collaborative networks.

- **Mental Health:** Karen J. Coleman, PhD, is the site principal investigator for the Mental Health Research Network (MHRN), a national network involving 10 health systems funded by the NIH/ National Institute of Mental Health. The MHRN is designed to conduct population-based mental health research that can be effectively translated into clinical practice. Several projects are ongoing as a part of this effort including an Autism Spectrum Disorder registry and studies of how mental health practices vary across medical settings.
- **Diabetes:** Jean M. Lawrence, ScD, MPH, MSSA is the site principal investigator for SUPREME-DM (Surveillance, Prevention, and Management of Diabetes Mellitus) study, a multi-institutional consortium for comparative effectiveness research in diabetes prevention and treatment. Bringing together researchers from 12 integrated health care systems with more than 11 million members, including 750,000 people with diabetes, the consortium aims to link clinical and administrative information to conduct cutting-edge research.

Industry Grants

In addition to federally funded grants, R&E scientists have been successful in obtaining funds from industry. Aniket Kawatkar, PhD, is the principal investigator for the following grants:

- **Oncology:** This study, which spans a 10-year time horizon, will estimate the incidence rate, treatment management patterns, resource utilization and expenditure, and mortality outcomes associated with febrile neutropenia in KPSC members with non-Hodgkin's lymphoma, breast cancer, and lung cancer.
- **Diverticulitis:** This study will set up a health-related quality of life assessment to inform a cost-effectiveness model comparing mesalamine and standard-of-care empirical treatment. This study is unique in that it evaluates changes experienced by diverticulitis patients within 48 hours of a patient presenting with an acute episode.

Renewed Grants

The CDC awarded more than \$3 million to support the next five years of the SEARCH for Diabetes in Youth Study, a multi-center observational study. Jean M. Lawrence, ScD, MPH, MSSA, is the principal investigator.

Publications Overview

Research produced in Southern California continues to be published in some of the top journals in the field, including the *New England Journal of Medicine*, the *Journal of the American Medical Association*, the *American Journal of Public Health*, and other prominent scientific publications.

In 2010, R&E scientists and medical center physicians published more than 200 articles in peer-reviewed journals. More than 90 were first-author articles.

These studies garnered significant positive press for the organization. Based on Kaiser Permanente Program Offices data through mid-December, research stories accounted for 37 percent of all positive news coverage about Kaiser Permanente Southern California in 2010.

The following are a partial listing of first-author articles published by KPSC researchers. For a complete listing of studies published by R&E faculty as well as studies published by medical center physicians, see the Bibliography section.

Diabetes

Clinical outcomes of pregnancies complicated by mild gestational diabetes differ by combinations of abnormal oral glucose tolerance test values

Authors: Mary Helen Black, PhD; David A. Sacks, MD; Anny H. Xiang, PhD, MS; and Jean M. Lawrence, ScD, MPH, MSSA

Journal: Diabetes Care

Gestational diabetes: risk of recurrence in subsequent pregnancies

Authors: Darios Getahun, MD, MPH; Michael J. Fassett, MD; and Steven J. Jacobsen, MD, PhD

Journal: American Journal of Obstetrics and Gynecology

Prevalence and timing of postpartum glucose testing and sustained glucose dysregulation after gestational diabetes mellitus

Authors: Jean M Lawrence, ScD, MPH, MSSA; Mary Helen Black, PhD; Jin-Wen Hsu, PhD; Wansu Chen, MS; and David A Sacks, MD

Journal: Diabetes Care

Cancer

Red wine consumption not associated with reduced risk of colorectal cancer

Authors: Chun Chao, PhD, MS; Reina Haque, PhD, MPH; Bette J. Caan, DrPH; Kwun-Yee T. Poon, MS; Hung Fu Tseng, PhD, MPH; and Virginia P. Quinn, PhD, MPH

Journal: Nutrition and Cancer

Red wine consumption and risk of prostate cancer: the California Men's Health Study

Authors: Chun Chao, PhD, MS; Reina Haque, PhD, MPH; Stephen K. Van Den Eeden, PhD; Bette J. Caan, DrPH; Kwun-Yee T. Poon, MS; and Virginia P. Quinn, PhD, MPH

Journal: International Journal of Cancer



Publications Overview

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Treatment of ductal carcinoma in situ among patients cared for in large integrated health plans

Authors: Reina Haque, PhD, MPH; Ninah S. Achacoso, MS; Suzanne W. Fletcher, MD, MSc; Larissa Nekhlyudov, MD, MPH; Laura C. Collins, MBBS; Stuart J. Schnitt, MD; Charles P. Quesenberry Jr, PhD; and Laurel A. Habel, PhD

Journal: The American Journal of Managed Care

Eye Research

Intravitreal bevacizumab and ranibizumab for age-related macular degeneration a multicenter, retrospective study

Authors: Donald S. Fong, MD, MPH; Peter Custis, MD; Jennifer Howes, PhD; and Jin-Wen Hsu, PhD

Journal: Ophthalmology

Obesity

Extreme childhood obesity is associated with increased risk for gastroesophageal reflux disease in a large population-based study

Authors: Corinna Koebnick, PhD, MS; Darios Getahun, MD, MPH; Ning Smith, MS; Amy H. Porter, MD; Jack K. Der-Sarkissian, MD; and Steven J. Jacobsen, MD, PhD

Journal: International Journal of Pediatric Obesity

Prevalence of extreme obesity in a multiethnic cohort of children and adolescents

Authors: Corinna Koebnick, PhD, MS; Ning Smith, MS; Karen J. Coleman, PhD, MS; Darios Getahun, MD, MPH; Kristi Reynolds, PhD, MPH; Virginia P. Quinn, PhD, MPH; Amy H. Porter, MD; Jack K. Der-Sarkissian, MD; and Steven J. Jacobsen, MD, PhD

Journal: The Journal of Pediatrics

Body weight and height data in electronic medical records of children

Authors: Ning Smith, MS; Karen J. Coleman, PhD, MS; Jean M. Lawrence, ScD, MPH, MSSA; Virginia P. Quinn, PhD, MPH; Darios Getahun, MD, MPH; Kristi Reynolds, PhD, MPH; Wansu Chen, MS; Amy H. Porter, MD; Steven J. Jacobsen, MD, PhD; and Corinna Koebnick, PhD

Journal: International Journal of Pediatric Obesity

Orthopedic Care

Kaiser Permanente National Total Joint Replacement Registry: aligning operations with information technology

Authors: Elizabeth W. Paxton, MA; Maria C.S. Inacio, MS; Monti Khatod, MD; Eric J. Yue, MD; and Robert S. Namba, MD

Journal: Clinical Orthopaedics and Related Research

A prospective study of 80,000 total joint and 5000 anterior cruciate ligament reconstruction procedures in a community-based registry in the United States.

Authors: Elizabeth W. Paxton, MA; Robert S. Namba MD; Gregory B. Maletis, MD; Monti Khatod, MD; Eric J. Yue, MD; Maria C.S. Inacio, MS; and T. Ted Funahashi, MD

Journal: Journal of Bone and Joint Surgery (American)

Vaccine Safety and Effectiveness

Pneumococcal vaccination and risk of acute myocardial infarction and stroke in men

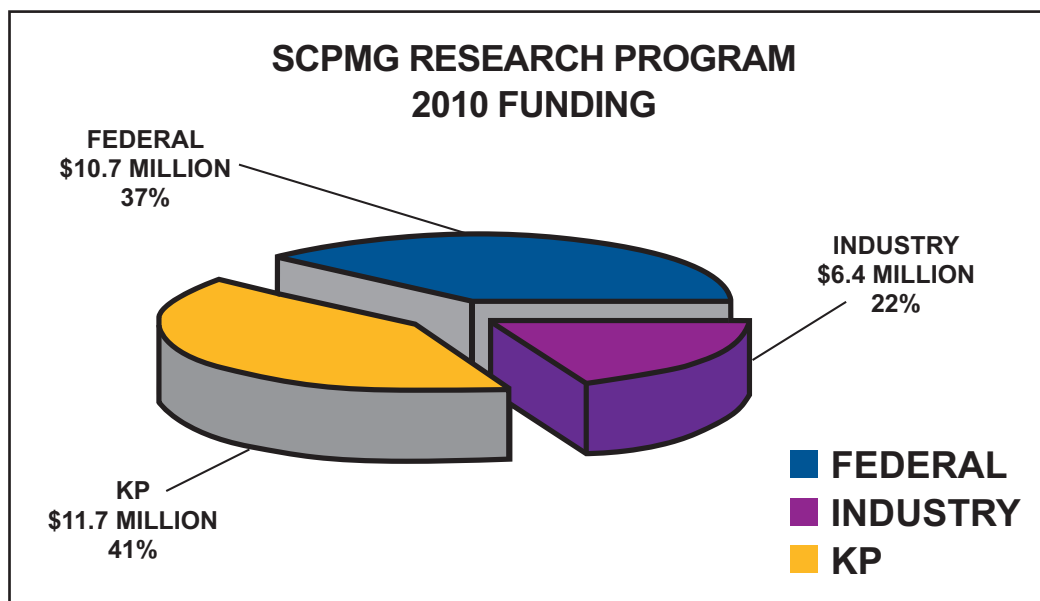
Authors: Hung Fu Tseng, PhD, MPH; Jeffrey M. Slezak, MS; Virginia P. Quinn, PhD, MPH; Lina S. Sy, MPH; Stephen K. Van Den Eeden, PhD; and Steven J. Jacobsen, MD, PhD

Journal: *Journal of the American Medical Association (JAMA)*

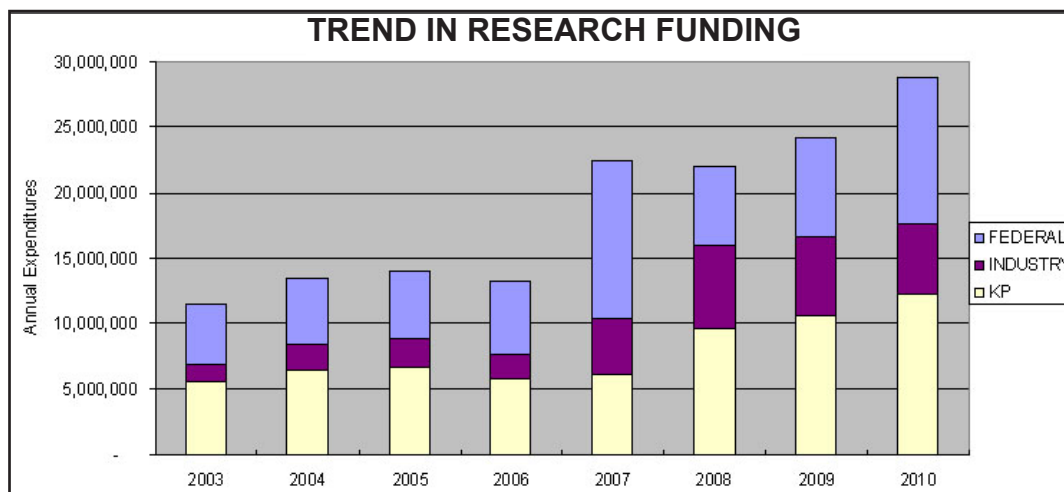
Research Funding

Extramural funding has risen significantly in the past six years, rising from \$6.9 million in 2004 to \$16.6 million in 2010.

2010 Funding Total: \$28.8 (based on actual expenditures)



Sources of funding for research in Southern California include federal grants and industry contracts, as well as funding from SCPMG and Kaiser Permanente's Community Benefit program.



Research funding has increased significantly in the past two years.



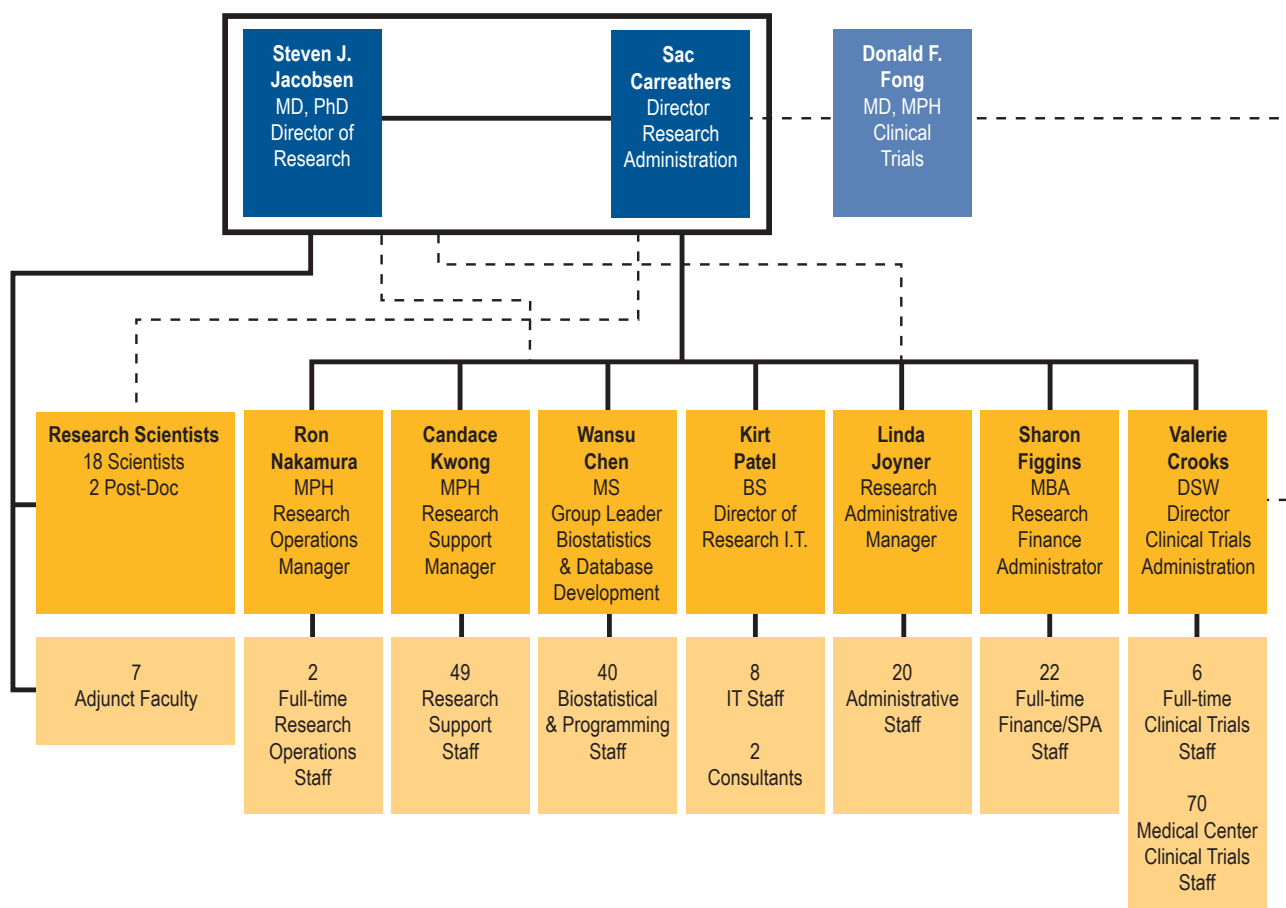
Department Overview

R&E is structured into eight business units having specific disciplines that work as cross-functional teams to support scientific research.

- Research Scientists
- Biostatistics, Programming, and Database Development
- Clinical Trials
- Research Support
- Administrative Support
- Research Finance Office/Sponsored Projects Administration
- Research IT
- Research Operations

Research & Evaluation

12/2010



Services

R&E provides an array of services to SCPMG physicians and KPSC staff interested in the conduct of research.

Consultation: critiques of written hypotheses and research questions; assistance with study design and written study protocols; suggestions for funding sources; guidance for study implementation and data collection plans; data analysis and interpretation; and written and/or oral presentations of research.

Analysis: consultation on study design and choices/application of statistical methods; power and sample size calculation; programming and data management; data analysis using statistical software and interpretation of results; assistance in manuscript preparation for publication and abstract submission; consultation on KPSC electronic data systems and data-quality issues.

Data Management: the development and management of large databases such as the Mortlink I and II systems, and the Diabetes Research Case Identification Database.

Education: the Department sponsors monthly Journal Clubs, Department Seminars and Administrative Grand Rounds designed to expose and educate our research cadre to current research, journal articles and federal regulations related to the conduct of research.

Fiscal and Programmatic Services: Sponsored Programs Administration (SPA) and the Research Finance Office (RFO) provide the fiscal and programmatic management of our external and internal research projects.



Institutional Administrative Responsibilities

R&E administers all extramurally funded project research activity, ensuring compliance with federal, state, and local regulations (including OMB Circular A-110 and OMB A-122), institutional policies, and good business practices for assurance of proper stewardship on behalf of the sponsor and the institution.

The Department supports KPSC researchers in identifying potential funding sources, preparing and reviewing proposals, and communicating with funding agencies.

Once an award has been granted, R&E provides the following support:

- Notifying recipients of awards.
- Establishing cost centers.
- Preparing subcontracts.
- Ensuring compliance with sponsor and institutional regulations.
- Reviewing and approving expenditures.
- Assisting with reporting and compliance requirements.
- Submitting close-out documents.

R&E also oversees post-award fiscal compliance of all extramural sponsored projects in accordance with the appropriate fiscal regulations to include the federal OMB A-133 regulations. The Department provides sponsors with invoices and expenditure reports in accordance with generally accepted accounting principles, as well as sponsor and institutional (Kaiser Permanente) policies.

Scientific Environment and Resources

KPSC presents a unique opportunity for scientists and physicians engaged in research. It is an ideal environment for population-based epidemiologic, clinical and health services research, owing largely to the underlying population, model of care delivery, and the information infrastructure supporting the practice and business that can be leveraged for research purposes.

Diverse Patient Population

KPSC serves more than 3.4 million members. These members reflect the diversity of the region; they represent more than 250 different ethnicities and speak about 120 different languages. This racial and ethnic diversity affords opportunities for researchers to gain unique insights into health disparities.

Integrated Health Care and Electronic Medical Records

Kaiser Permanente's integrated structure allows the health plan, hospitals, and medical group to work together in a coordinated fashion for the benefit of the patient. Records are linked by a robust electronic medical record, Kaiser Permanente HealthConnect®, allowing researchers to look at conditions and health outcomes across the care continuum.

Research Technology

R&E has a rich array of information technology resources that support scientific inquiry. Data warehouses, for example, integrate confidential patient information ranging from utilization to mortality, with some records dating back as far as 1980. The Department maintains several registries, which support patient care and research efforts, as well as case identification databases and other research tools.

Laboratory & Specimens

The Southern California Permanente Medical Group Regional Reference Laboratories comprise a sophisticated laboratory management system that interfaces with Kaiser Permanente's medical centers and medical office buildings. Services include comprehensive chemistry, microbiology, cellular pathology, cytogenetic testing, and anatomic pathology services based on state-of-the-art instrumentation and methodologies.

Evidence-Based Medicine

The Southern California Permanente Medical Group, the physician organization that serves Kaiser Permanente members in the region, has a long-standing commitment to evidence-based medicine. Researchers have opportunities to collaborate with our clinicians in a variety of ways, from conducting research to translating findings.



Faculty Research Programs

R&E scientists carry out a program of research and conduct program evaluations spanning a range of areas, including

Clinical Research looks at which treatments work, how well they work, and which work better than others. Treatments under study can range from vaccines to cancer screening tests, and include drugs and new medical devices.

Epidemiological Research examines possible causes of disease in specific populations. This research has focused on smoking and cancer, video display terminals, genetic defects, and other topics.

Health Services Research helps develop greater knowledge about the most effective ways to deliver and finance care, improve access to care, and enhance patient satisfaction.

Behavioral Research examines the role of behavioral interventions to improve health and prevent disease.

Specific research interests include:

- | | |
|---------------------------------|------------------------------------|
| ■ Aging | ■ Injury |
| ■ Cancer | ■ Kidney Diseases |
| ■ Cardiovascular Disease | ■ Maternal and Child Health |
| ■ Child and Adolescent Health | ■ Medication Adherence |
| ■ Comparative Effectiveness | ■ Men's Health |
| ■ Diabetes | ■ Mental Health |
| ■ Digestive System Disorders | ■ Molecular Epidemiology |
| ■ Eye Research | ■ Neurological Disorders |
| ■ Genetics | ■ Obesity |
| ■ Gestational Diabetes Mellitus | ■ Pharmacoepidemiology |
| ■ Health Economics | ■ Prevention and Behavior Change |
| ■ Health Equity | ■ Quality Improvement |
| ■ Health Informatics | ■ Vaccine Safety and Effectiveness |
| ■ Health Services Research | ■ Violence and Abuse |
| ■ HIV/AIDS | ■ Women's Health |

The common thread throughout this broad range of research is a focus on translation—how the research findings can change practice in near term.



Research Scientists



Annette Adams, PhD, MPH | Research Scientist I

Dr. Adams's research interests have primarily focused on orthopedic injuries, particularly of the hip and lower extremities. She has focused primarily on injuries in older adults, and has a particular interest in examining hospital-level influences and the effects of processes-of-care on outcomes in these patients. She also has an interest in studying injuries in children. Finally, she has begun examining how pre-existing and co-morbid conditions affect outcomes in patients undergoing hip or knee arthroplasty.



Chun Chao, PhD, MS | Research Scientist I

Adjunct Assistant Professor, University of California at Los Angeles, Epidemiology, Los Angeles, California

Dr. Chao is interested in the following research areas: (1) identification of risk and protective factors for cancer; (2) identification of prognostic biomarkers for cancer disease progression; (3) identification of predictors for adverse events associated with cancer treatment; and (4) utilization of HPV vaccine. Currently, she is leading several cancer epidemiology projects with an emphasis on non-Hodgkin lymphoma and HIV-related malignancies. She is particularly interested in tissue-based research. Her other studies examine the risk/protective factors for cancer development, including the role of certain dietary intake, pharmacological agents and immunomodulation.



Craig Cheetham, PharmD, MS | Pharmacist

Dr. Cheetham received his Doctor of Pharmacy and a Masters in Pharmaceutical Economics from the University of Southern California, School of Pharmacy. He practiced hospital-based clinical pharmacy for nearly 20 years before moving into his current position as a researcher within the Pharmacy Analytical Services Department at Kaiser Permanente in Southern California. His interests include drug and vaccine safety, health services research and pharmaceutical outcomes.



Karen J. Coleman, PhD, MS | Research Scientist II

Adjunct Associate Professor, San Diego State University, Graduate School of Public Health, San Diego, California

Dr. Coleman is interested in the behavioral, social, and environmental determinants of child, adolescent and adult obesity. She is trained as a behavioral interventionist and has conducted several school health studies to reduce child obesity in low-income, primarily minority school districts. She is currently creating a registry of KPSC patients who have had weight loss surgery for research and patient care management. She is also the lead investigator for KPSC in the national Mental Health Research Network funded by the National Institute of Mental Health. Her specific interests in this area are cross-cultural mental health promotion and measurement as well as the role of mental illness/health in the etiology of child, adolescent, and adult obesity.

Kim Danforth, ScD, MPH | Research Scientist I

Dr. Danforth has broad interests in health research and has studied a wide range of risk factors (lifestyle factors/questionnaire data, circulating markers, and genetic data) and outcomes, including research on urinary incontinence and ovarian, prostate, endometrial, and colorectal cancers. She has conducted prospective, nested case-control, and cross-sectional analyses of several large cohort studies. Dr. Danforth's focus on answering practical research questions brought her to Kaiser Permanente, where she has been participating in the development of a national Kaiser Permanente Center for Effectiveness and Safety Research.

**Stephen F. Deroose, MD, MS | Research Scientist I**

Dr. Deroose focuses his research on primary and secondary prevention of chronic disease at the individual and population level. He uses a variety of research methods to address questions regarding clinical care delivery and outcomes. His areas of interest include chronic kidney disease, sleep disorders, cardiovascular disease, diabetes, and emergency department outcomes.

**Darios Getahun, MD, MPH | Research Scientist I**

Clinical Assistant Professor, University of Medicine and Dentistry New Jersey-Robert Wood Johnson Medical School, Obstetrics and Gynecology, New Brunswick, New Jersey

Dr. Getahun's current research focus and interests include population-based studies related to perinatal and child health issues, successive pregnancy outcomes, fetal origin of childhood diseases, asthma morbidity and mortality, and health disparities. Dr. Getahun is interested in studying the heritability of various adverse perinatal outcomes among singleton and multiple births to further examine the contribution of genetic factors and factors due to shared intrauterine factors. He is also a member (co-investigator) of the research team that is exploring the impact of medication use in pregnancy on adverse perinatal outcomes in Kaiser Permanente members.

**Reina Haque, PhD, MPH | Research Scientist I**

Dr. Haque is a cancer epidemiologist in the Department of Research & Evaluation, and also serves as the scientific advisor to the KPSC tumor registry. Her research interests include: pharmacoepidemiology; cancer screening; and molecular markers of prognosis and cancer survivorship. She has led studies on breast, colorectal, and prostate cancer, and has worked with electronic health records related to cancer incidence, treatment, cancer recurrence, pathology, and pharmaceutical use. Currently, she is leading a multi-site study that examines common drug interactions in a large cohort of breast cancer survivors.





Jason Jones, PhD | Research Scientist II

Adjunct Assistant Professor, University of Utah, Biomedical Informatics, Salt Lake City, Utah

Dr. Jones' goal is to demonstrate to clinicians and patients that they will benefit from providing clinically relevant data by receiving improved clinical decision support. His research focuses on patient identification, risk prediction, and treatment strategy selection around emergency department and inpatient encounters. Examples include: rapid identification of patients with sepsis in the emergency room; prediction of venous thrombosis in hospitalized patients; and hospital admission decision support for patients with community acquired pneumonia. To maximize the clinical utility of existing electronic health and administrative data, Dr. Jones has spent time developing methodologies for storing, retrieving, analyzing, and presenting medical data from the individual patient encounter to the population levels.



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

Research Professor of Preventive Medicine, Keck School of Medicine, University of Southern California

A chronic disease epidemiologist by training, Dr. Jacobsen is the principal investigator on two large, pivotal post-licensure vaccine safety studies and the site principal investigator for the KPSC Vaccine Safety DataLink site. He served as the lead epidemiologist for a variety of population-based studies, including studies of vaccine safety and immunogenetics, rheumatoid arthritis, and many chronic diseases. He has authored or co-authored more than 350 peer-reviewed manuscripts and has served on the editorial board of the American Journal of Epidemiology since 1997. He also was a charter member of the Epidemiology and Disease Control Study Section 1 from 1997 to 2001 for the Center for Scientific Review, National Institutes of Health and has served on and chaired numerous Special Emphasis Panels.



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

Dr. Kawatkar's broad research interests are in health inequity/disparities, health care/pharmaceutical utilization and associated economic, clinical and humanistic outcomes. Dr. Kawatkar utilizes established methods from econometrics, cost-effectiveness, conjoint analysis and net benefit analysis, to evaluate intervention/treatments aimed to improve patient care in real-world clinical settings. His research focus at Kaiser Permanente is in advancing methods and understanding in comparative effectiveness, medication compliance and persistence, cost/expenditure data modeling, health related quality of life and health utility elicitation in chronic diseases.



Corinna Koebnick, PhD, MS | Research Scientist II

Dr. Koebnick is an obesity epidemiologist. Her primary research focus is to investigate health consequences of obesity in children and young adults. These health consequences include conditions that are associated with chronic inflammation, increased cardiovascular disease risk, metabolic syndrome, and some cancers. Her current research involves extreme childhood obesity and the risk for gastroesophageal reflux disease, psoriasis, rheumatic diseases, gallstones, polycystic ovary syndrome, hypertension, dyslipidemia, and disturbed glucose metabolism. A secondary research focus is the association between obesity and cancer in young adults and health services research for obese patients. Future research is targeted towards evaluation of the cumulative health effects of excessive body weight in extremely obese individuals.

Jean M. Lawrence, ScD, MPH, MSSA | Research Scientist II

Research Associate Professor, Keck School of Medicine, University of Southern California, Preventive Medicine, Los Angeles, California

Dr. Lawrence's research focuses on type 1 and type 2 diabetes in children, adolescents, and young adults, and pregestational diabetes and gestational diabetes mellitus (GDM) among childbearing women. Dr. Lawrence is the Principal Investigator for the California Center of the SEARCH for Diabetes in Youth Study where she focuses on epidemiologic studies of diabetes, risk factors for short and long-term complications, as well as the impact of diabetes on quality of life, including depression. Among childbearing women, her work examines trends and risk factors for GDM, postpartum glucose screening and follow-up, antidiabetic medication use prior to and during pregnancy, and progression to type 2 diabetes. An emphasis on identifying health disparities underpins much of this work.



Annette M. Langer-Gould, MD, PhD, MS | Research Scientist I

Associate Clinical Professor, University of Southern California, Keck School of Medicine, Los Angeles, California

Dr. Langer-Gould's research interests include multiple sclerosis, neuroepidemiology, prognosis of chronic diseases, novel randomized controlled clinical trial designs, and the role of biomarkers and surrogate outcomes in clinical research. She has conducted studies on pregnancy and the modulation of multiple sclerosis and is conducting a study on the role of vitamin D and genotype on the risk of developing multiple sclerosis. Dr. Langer-Gould is a practicing neurologist at the Kaiser Permanente Los Angeles Medical Center.



Marlene Lugg, DrPh, MPH | Research Scientist I

Adjunct Professor, West Coast University, Health Care Administration, Los Angeles, California

Dr. Lugg's research interests are mainly in three areas: (1) studies of immunization practices, quality, and vaccine safety; (2) development of Health Information Systems including data linkage and immunization tracking systems (registries); and (3) the causes and control of accidental injury.



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

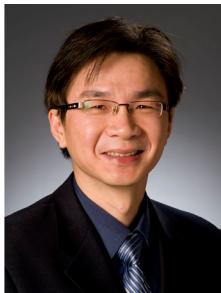
Dr. Quinn is a behavioral health and health services researcher. Her research focus includes the development and testing of interventions for changing diet, physical activity, smoking, and adherence to medications/medical treatment in diverse patient populations and families. Her research interests in the area of quality of care include breast cancer treatment, screening, tobacco policy, and treatment for psychosocial distress.





Kristi Reynolds, PhD, MPH | Research Scientist I

Dr. Reynolds is an epidemiologist with research interests in the etiology, prevention, and treatment of cardiovascular disease. Her work includes studies of risk factors for heart disease, stroke, diabetes and end-stage renal disease; trends in diabetes, obesity and cardiovascular disease rates; prevention of hypertension and stroke; and quality of care among overweight and obese patients. Dr. Reynolds serves on the KPSC Medication Adherence Steering Committee and is involved in interventions to improve medication adherence. She is a former scholar of the NIH-funded Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program. Currently, Dr. Reynolds serves on the Diabetes Care and Hypertension editorial boards and is the site principal investigator for several NIH- and AHRQ-funded collaborations.



Hung-Fu Tseng, PhD, MPH | Research Scientist II

Dr. Tseng's work focuses on infectious diseases and vaccine safety/effectiveness. Specific areas of interest include zoster, varicella, rubella, hepatitis B, Japanese encephalitis vaccines, pneumococcal conjugate vaccine in children, and pneumococcal polysaccharide vaccine in adults. He has led several multicenter studies and has expertise in analytical methods for a variety of study designs employed in vaccine safety and effectiveness. He is currently the Principal Investigator for three Vaccine Safety DataLink studies funded by CDC, the ZOSTAVAX™ vaccine safety study, the PCV 13 Rapid Cycle Analysis study, and the Tdap for off-label elderly users.



Anny Hui Xiang, PhD, MS | Research Scientist Biostatistician III

Adjunct Research Associate Professor, Department of Preventive Medicine, USC, Keck School of Medicine, Los Angeles, California

As an investigator and applied biostatistician, Dr. Xiang uses statistical methodology to understand disease development and conduct clinical trials in disease prevention/intervention. Her focus has been on been diabetes, cardiovascular disease, and obesity control. She has extensive experience designing, conducting, planning and executing data analysis for observational epidemiological studies and clinical trials. Dr. Xiang is interested in understanding gene and environmental factors in diabetes risk; racial/ethnic differences in risks of various diseases associated with gestational diabetes; methodological investigation of biostatistical questions arising from research studies; collaborating with researchers investigating etiology/biology/risk factors for disease development and drug safety; and designing appropriate clinical trials to assess treatment/intervention efficacy and effectiveness.

Post Doctoral Research Fellows

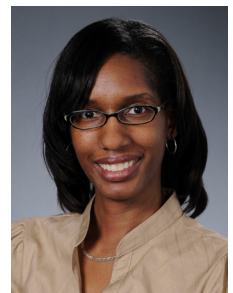
Rulin C. Hechter, MD, PhD

Dr. Hechter's research interests include vaccine safety and effectiveness, racial/ethnic disparities in HIV infection and utilization of preventive services, and HIV infection associated non-AIDS diseases.



Kim Porter, PhD, MPH

Dr. Porter has an interest in various aspects of cancer research such as epidemiology and prevention, outcomes and survivorship, epidemiologic methods, and health disparities. At present, her research focuses on prostate cancer. Her current work examines racial/ethnic differences in the interval from diagnosis to treatment after a diagnosis of prostate cancer. She is also Co-Investigator for the Computer-based Quality of Life Survey Outcomes for Patients Undergoing Treatment for Prostate Cancer Study.



Lauren P Wallner, PhD, MPH

Dr. Wallner's research interests include understanding the determinants, outcomes and utilization of health services associated with cancer and other chronic diseases. Specifically, her research focuses on benign and malignant urologic conditions such as prostate cancer, urinary incontinence and benign prostatic hyperplasia. Her recent projects include understanding the role obesity and diabetes play in influencing the development and detection of prostate cancer, determining what factors influence men to screen for prostate cancer, understanding the treatment decision-making process for newly diagnosed patients, and understanding health behaviors and health services utilization among prostate cancer survivors. She is also interested in identifying new ways to apply epidemiologic and cross-disciplinary methods to further our understanding of these chronic conditions.





Associate Investigators

Somjat S. Brar, MD, MPH | Adjunct Investigator

Dr. Brar's research interests include: (1) the role of medical devices and medications in the management of patients with cardiovascular diseases; (2) comparative-effectiveness of medical devices, strategies, and medications for the management of coronary artery disease and related outcomes; (3) predictors, outcomes, and therapies for contrast medium-induced nephropathy; (4) rare cardiomyopathies; and (5) meta-analysis and decision making processes in cardiovascular medicine.

R. James Dudl, MD | Adjunct Investigator

Dr. Dudl's research interests include population level cardiovascular disease prevention and glucose control in patients with diabetes.

Vincent J Felitti, MD | Adjunct Investigator

For the past 15 years, Dr. Felitti has been co-principal investigator for the Adverse Childhood Experiences (ACE) Study, a retrospective and prospective analysis of the prevalence and long-term impact of ten categories of adverse childhood experiences in 17,400 adult Kaiser Permanente members.

George F. Longstreth, MD | Adjunct Investigator

Dr. Longstreth is interested in gastrointestinal epidemiology, functional gastrointestinal disorders, acute large bowel ischemia, diverticulitis, and medical anthropology.

S. Michael Marcy, MD | Adjunct Investigator

Dr. Marcy's research interests include vaccine efficacy and safety, management of infectious diseases in office practice and appropriate and judicious use of antimicrobials.

David Sacks, MD | Adjunct Investigator

Dr. Sacks' current research interests include prevention of gestational diabetes, establishing norms for maternal glycemia during labor, and the maternal and fetal consequences of early delivery of women who have diabetes.

Robert S. Zeiger, MD, PhD | Adjunct Investigator

Dr. Zeiger's research interests include prevention of asthma and allergic disorders, clinical asthma trials of comparative treatments, cost analysis of asthma and allergic disorders, and outcomes research.

Business Unit Reports

Biostatistics, Programming and Database Development

The Biostatistics, Programming and Database Development unit works closely with the research scientists and other members of the research team, gathering information and providing analytical support to address research questions. The team's experienced biostatisticians and SAS/analytical programmers are dedicated to the production of quality products and the highest level of scientific integrity.

The unit has continued to expand over the past few years. As of December 2010, the unit has more than forty PhD and Master's-level biostatisticians, programmers, and database/application developers, as well as a natural language processing specialist and project managers.

The Biostatistics Unit supports approximately 345 research projects, including 233 analytical research projects and 112 consultation projects. The group provides data extraction and management, data analysis, and statistical consultation for projects in R&E and throughout KPSC.



Selected 2010 Accomplishments

The unit provided the following statistical/programming services in 2010:

- 112 consultation or feasibility studies.
- 103 Institutional Review Board (IRB)-approved, internally funded (including Regional Research Committee) studies.
- 99 IRB-approved, externally funded studies.
- 31 IRB-approved, internally funded R&E scientists' projects.

Increased Productivity

Key Accomplishments

- Supported 233 analytical research projects, including 99 externally funded research projects, 31 internally funded R&E scientists' projects, and 103 internally funded physician projects.
- Provided consultation on 112 projects (92 for physicians and 20 for R&E scientists). These include feasibility studies, preliminary data analysis for grant or IRB submission, and consultation on study design, statistical methods, and sample size/power estimation.
- Participated in a total of seven patient care management and clinical quality/assurance reports.
- Authored or co-authored 39 papers in peer-reviewed journals, including three first author publications and three papers based on data from outside Kaiser Permanente.

Supported Patient Care Management and Clinical Quality/Assurance Reporting

Key Accomplishments

- Continued to maintain the Bariatric Surgery Registry and the corresponding web application, provided timely report and technical support for users.
- Continued to support the HIV patient care management activities including the HIV automated report delivery system and monitored and modified records per requests.
- Modified data extraction, transformation, and loading process based on Clarity SU09 upgrade to update echocardiogram reports with ejection fraction (EF) values, and fed these data into POINT for patient and panel management.
- Designed and built Prostate Cancer Registry web application.

Database Infrastructure and Application Development and Enhancement

Key Accomplishments

- Developed/enhanced research databases which include Inpatient Pharmacy, Inpatient Vital Sign, Common Provider Master, Computerized Oncology Profile System, MUSE Cardiology Information System, Allergy, Patient History, eReferral, and Order.
- Implemented, developed and enhanced the following applications: Cancer Text Information Extract System, Research Database Reference Tool, Research Preliminary Data Application, and Project Protocol Management System.
- Developed and conducted linkages between KPSC members and California births (2003-2007), deaths (2008), and Social Security Administration deaths (2009).
- Implemented Version 3 of Virtual Data warehouse which is funded by Kaiser Permanente's Center for Effectiveness & Safety Research (CESR). Developed a set of programs/views to standardize data formats/codes to facilitate multi-side studies.
- Migrated SAS/ORACLE Research Data Warehouse and research projects from KP-IT Analytical Center for Excellence environment to R&E working environment at Irvine Data Center.
- Configured R&E SAS Metadata servers and Oracle database servers in IDC.

Customer Service Focus

Key Accomplishments

- Maintained a high level of customer satisfaction (95 percent).
- Maintained good relationships with our customers that included KP physicians and R&E scientists, as well as outside collaborators and sponsors.

First Author Publications

- **Smith N**, Coleman KJ, Lawrence JM, Quinn VP, Getahun D, Reynolds K, **Chen W**, Porter AH, Jacobsen SJ, Koebnick C. Body weight and height data in electronic medical records of children. *Int J Pediatr Obes*. 2010 May 3;5(3):237-242.
- **Smith N**, Iyer R, Langer-Gould A, Getahun D, Strickland D, Jacobsen SJ, **Chen W**, Derose S, Koebnick C. Health plan administrative records versus birth certificate records: quality of race and ethnicity information in children. *BMC Health Serv Res*. 2010;10:316.
- **Black MH**, Sacks DA, Xiang AH, Lawrence JM. Clinical Outcomes of Pregnancies Complicated by Mild Gestational Diabetes Mellitus Differ by Combinations of Abnormal Oral Glucose Tolerance Test Values. *Diabetes Care*. 2010;33(12):2524-2530.



Clinical Trials Research Program

The Southern California Permanente Clinical Trials Regional Office (CTRO) promotes research that advances clinical practice in order to improve health outcomes. Clinical Trials provide KPSC members access to the latest advances in medicine, and offer SCPMG physicians the opportunity to participate in the development of new treatments.

The Southern California program supports a wide range of clinical research projects, from small pilot studies to drug and device trials, outcomes, and quality-of-life analyses. The Clinical Trials team has experience with Phase II to Phase IV.

Clinical Trial investigators are practicing physicians who bridge the gap between research and clinical practice. Physicians throughout the region conduct trials involving the prospective study of investigational drugs, devices, and interventions.



Selected 2010 Accomplishments

Our SCPMG supported clinical trials continue to be the top enroller for a number of important studies. Our contract with the Contract Research Organization (CRO), Quintiles, has provided access to 10 active studies with a total of 78 members enrolled for 2010. These studies focused on infectious disease, oncology, obstetrics/gynecology, dermatology, and cardiology.

Access to Clinical Trials

SCPMG physicians added 63 new clinical trials for a total of 348 active clinical trials. A total of 60 physicians serve as principal investigators, with seven joining in 2010.

Quality

The Clinical Trials Regional Office conducted quality assurance reviews at 47 sites for 38 principal investigators conducting active clinical trials.

The following two external audits were conducted:

- Food and Drug Administration: Successful, with no further action required.
- Cooperative group audits: Completed with full 3-year accreditation.

Service

The Clinical Trials Regional Office assists new investigators in all trial start-up activities such as protocol review, site qualification, Institutional Review Board application, completion of regulatory documents, research training, and site management.

In 2010, the office received 110 contacts from outside sponsors and Contract Research Organizations regarding their interest in conducting clinical trials, signed 46 confidentiality agreements, and conducted additional interest and feasibility assessments. In addition, trial initiation activities were provided for 15 new projects. Ongoing regulatory support – including protocol and consent modifications, serious adverse events reporting, continuing review reports, data completion and resolving queries, and investigational new drug safety reports – was provided to four trial sites.

Clinical Trials Research Program

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Cost Offsets

Drug cost offsets in 2010 exceeded \$3.8 million for selected clinical trials programs.

- Cancer Clinical Trials Access Program: \$2,400,000
- HIV/AIDS Research Trials Program: \$795,916
- Surgical Radiation Oncology Clinical Trials Access Program: \$15,000
- Pediatric Oncology Research: \$328,000
- Hepatology Research: \$382,091

Cancer Clinical Trials Access Program (CCTAP)

Principal Investigators: Jonathan Polikoff, MD and Han Koh, MD

The Cancer Clinical Trials Access Program (CCTAP) provided access to 53 active oncology clinical trials in 2010. An additional 96 were open for follow-up. A total of 78 investigators enrolled 167 new members into studies.

In 2010, the program changed its major National Cancer Institute cooperative group affiliation to facilitate partnerships with our colleagues in KPNC as well as improve oncology protocols in the Beacon Oncology Information System.

HIV/AIDS Research Trials

Principal Investigator: William Towner, MD

The HIV/AIDS Research Trials (HART Program) conducted 17 active clinical trials in 2010, with approximately 67 enrolled patients. Patients received access to at least seven different Investigational New Drug (IND) treatments from these clinical trials.

The program has expanded its therapeutic areas of interest to include clinical trials in hepatitis, infectious disease, and vaccines. These trials are the beginning of the effort to increase clinical trial participation throughout SCPMG.

Kaiser Permanente/City of Hope Bone Marrow Transplant Research

Principal Investigators: Neil Kogut, MD and Ricardo Spielberger, MD

In 2010, a total of 147 Kaiser Permanente members received transplants at City of Hope. This is a decrease of 21 percent compared with last year's numbers. Of the 147 members, 139 were adults and 8 were pediatric. It is estimated that 1,024 KP members are in long-term follow-up post transplant.

Pediatric Oncology Investigational Trials Group

Principal Investigator: Robert Cooper, MD

The Pediatric Oncology Investigational Trials Group continues to support investigational trials sponsored by the Children's Oncology Group. In 2010, the group screened 108 patients and enrolled 84 patients into studies. The group currently has 95 trials open, with 10 opened in 2010 and 60 open to accrual.



Surgical Radiation Oncology Clinical Trials Access Program (SROCTAP)

Principal Investigator: Steve Vasilev, MD

In 2010 the program had 22 open protocols. The program opened six new studies in 2010 and enrolled twenty-six participants in SROCTAP trials this year. As of year-end, there were 25 patients on active treatment and 101 in follow-up.

The Gynecologic Oncology Group research protocols are also a part of the SROCTAP program under Dr Scott Lentz. Two new sites will open for recruitment in 2011, Irvine and San Diego. This expansion will greatly increase Gynecologic Oncology Group enrollment and the potential for drug cost savings.

Research Support

Research Support collaborates with scientists and other members of the research team to facilitate and implement epidemiologic, behavioral intervention, and observational research studies. Team members track operational aspects of research projects, assist with data collection, and offer consulting services, contributing to the overall quality of research produced in KPSC.

The team, which now includes more than 50 staff members, has continued to increase in size to meet the needs of new and ongoing projects. Areas of expertise include nutrition, HIV/ AIDS, vaccines, oncology, cardiovascular disease, women's health, diabetes, and more.



Selected 2010 Accomplishments

Facilitating Strategic Clinical Research

Research Support is collaborating with Neal Lonky, MD, chair of the Quality of Care Committee for the SCPMG Board of Directors, on a research project to determine which types of hysterectomy are best for patients with specific characteristics. Research Support helped build SmartSets—templates within KP HealthConnect to capture key data for the study—and conducted follow-up interviews.

Engaging SCPMG Physicians in Research

Research Support offered educational presentations at three medical centers, provided in-depth consultation to more than 20 physician researchers, and supported more than 20 researchers through the Institutional Review Board and Human Subjects Training. Research Support partnered with several KPSC Family Medicine residency programs to develop a joint research study.

Vaccine Research

The Research Support vaccine team initiated, implemented, and completed five studies as part of the Vaccine Safety Datalink. To support these studies, the team completed nearly 600 complex chart abstractions and more than 900 record validations. All deadlines to the Sponsor were met and the team received much praise for the quality of their efforts and processes. The Research Support vaccine team produced a total of 15 papers, abstracts, and posters.

Diabetes Research

Research Support continued its progress in identifying and screening individuals for type I, type 2, and gestational diabetes. The team conducted numerous case validations, chart abstractions, and case registrations. Over the course of the year, 200 new diabetes cases were identified through this project.

Research Support

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Oncology Research

Research Support worked on a number of oncology studies, coordinating and recruiting participants for each study. The Research Support team sent out thousands of mailings and attracted more than 700 individuals and families to participate in the various studies. The team also conducted extensive reviews of more than 1,400 charts. Additionally, the team produced a number of posters and presented on oncology research.

Cardiovascular Disease Research

Research Support supported various cardiovascular disease studies in 2010. The team conducted phone interviews and surveys, garnering a response rate of 60 percent and above. Site visits to KP medical centers were conducted to gain staff support and participation. The team abstracted medical records for nearly 5,000 electrocardiograms and nearly 770 stroke and hemorrhagic events among KPSC members diagnosed with atrial fibrillation.

Administrative Support

The Administrative Support Team (AST) provides day-to-day operational support for the research program, providing specialized research support and administrative assistance to the scientists and business units they support.

Each team member possesses a wide variety of skills, including project management, software expertise, travel planning, expense management, record keeping, and calendar management. All team members offer a high level of customer service and contribute their strong organizational skills to support efficient operations in the research program.

Research Administrative Analysts (RAAs)

RAAs act as business managers/liaisons for the scientists, performing the majority of administrative work to enable R&E faculty to concentrate on science. They submit abstracts, prepare presentations and posters for conferences, edit and revise manuscripts, submit manuscripts to journals, and provide assistance with submission of progress reports to funders. RAAs also support Clinical Trials and the Biostatistics unit.

Administrative Specialists IV

The Administrative Specialists IV provide administrative assistance for all unit managers, and also provide support for their units. The team supports the Research Support Group, Research Operations, Research IT, and the Leadership Team.

Selected 2010 Accomplishments

Supporting Expansion of R&E

The AST team has expanded as KPSC's research program has grown over past few years. In 2010, four new RAAs and four Administrative Specialists IV joined the team.

AST also provides support to every new team member who joins R&E. This includes providing a general department orientation and managing on-boarding of new scientists and staff. In 2010, the team supported the on-boarding of approximately 60 new team members.



Grant Submissions and Project Budgets

In 2010, the RAAs processed 71 grant submissions (33 primary and 38 sub-contracted).

As scientific projects get underway, the RAAs ensure budgets are managed properly. Based on the number of awards a scientist may receive, one analyst could have as many as 21 project budgets to manage each month.

Department Events

The team also assists with planning and organizing department events. In 2010, the team provided support for 13 Department Seminars and 12 Administrative Grand Rounds.

Research Finance

Research Finance is dedicated to providing high-quality support to the KPSC research program, specializing in Sponsored Project Administration (SPA) and Research Finance. Each team member works to ensure that research conducted at or in collaboration with KPSC complies with regulatory and institutional policies and guidelines.

Due to the complexity of research activities, team members are specially trained in research administration to assist and coordinate in the pre- and post-award administrative activities. This includes proposal development, budget development, contract negotiation, project accounting, reporting, and monitoring functions.



Research Finance Office

The Research Finance Office is responsible for overseeing post-award fiscal compliance of all extramural sponsored projects in accordance with A-133 regulations, federal administrative (OMB A110) and cost principle (OMB A122) guidelines, Generally Accepted Accounting Principles (GAAP) as well as institutional policies.

Institutional responsibilities include

- Providing sponsors with invoices and expenditure reports in line with generally accepted accounting principles as well as sponsor and institutional policy.
- Collecting payments and managing account receivables for extramural projects.
- Working with principal investigators and various project stakeholders to prepare and review payments to subcontractors assigned to extramural projects.
- Providing principal investigators and other project stakeholders with routine ad hoc reports and analysis for the effective management of cost center accounts.
- Preparing financial status reports and sponsored projects fiscal reporting for various key stakeholders, including sponsors, the R&E Executive Committees and SCPMG Board of Directors, the Kaiser Foundation Research Institute, Kaiser Permanente Direct Community Benefit Investment, and Kaiser Foundation Health Plan and Hospitals.
- Participating in the annual external audit in accordance with OMB-A-133 guidelines.

Research Finance

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Sponsored Projects Administration

SPA has the institutional responsibility for administration of all extramurally funded research activity. Oversight is performed in accordance with the appropriate federal regulations (including OMB Circular A-110 and OMB A-122), institutional policies and good business practices for assurance of proper stewardship on behalf of the sponsor and the institution.

SPA is responsible for all pre- and post-award management of all extramural sponsored projects. This includes federal and non-profit grants as well as industry clinical trials.

Institutional responsibilities include

- Assisting the principal investigator in preparation and submission of all aspects of grant application.
- Grant or contract negotiations with the sponsoring agency.
- Post-award monitoring, including modification or update of Notice of Award budgets as necessary, preparation of any modification or no cost extension request from sponsoring agency, and preparation of subcontracts.
- Assuring compliance with the sponsor and institutional requirements.
- Coordinating and responding to requests and/or audits from sponsors.
- Participating in the annual external audit in accordance with OMB A-133 guidelines.

Selected 2010 Accomplishments

Grant/Proposal Submission and Contracting Results

- A total of 256 grants and contracts were submitted in 2010 to external sponsors.
 - 158 of these submissions were awarded, contributing approximately \$14.1 and \$6.3 million in direct and indirect annual funding, respectively.
 - The potential cumulative impact to our research portfolio is approximately \$26.0 and \$9.5 million in direct and indirect funding, respectively.
- Clinical Trials executed 132 contracts, up from 69 in 2009, a 91 percent increase in volume. The team executed 80 percent of these contracts in less than 90 days; 66 percent were executed within 60 days.
- Total 2010 research expenses were \$28.8 million, up 18.6 percent from 2009.

Process Improvement Efforts

- Efforts to improve regional administrative and research operations included
 - Automation of the grant submission process through implementation of the Cayuse Grant Submission System.
 - Completion of Phase I specification for the IRIS Contract, Grants and Finance Administration Module implementation.
 - Automation of the patient stipend payment process through development and implementation of automated patient stipend check request system.
 - Automation of the monthly balance sheet reconciliation process.
 - Staffing changes to ensure adequate dedicated staffing for Clinical Trials and Federal SPA and Finance pre- and post-award activities.
 - Implementation of new fee schedule budget methodology for industry sponsored clinical trials to ensure adequate and consistent compensation in support of medical center protocol activities.

Compliance/Audit

- Successfully completed the 2009 A-133 Annual Audit with no material findings.
- Participated in the national Administrative Leadership Workgroup to address national research initiatives and national standards.
- Implemented the following Standard Operating Procedures related to records retention, signature authorization, gift card purchases, indirect cost waivers, the Cayuse business flow process, and close out procedures.

Training and Education

- Staff continued to maintain and develop their research management expertise by attending professional research organization seminars.
- Internal training programs continued throughout 2010 to ensure staff awareness and understanding of new policies and share best practices.

Research Information Technology

The Research Information Technology (IT) team ensures faculty and staff have access to the information technology infrastructure necessary to pursue scientific research. The team provides a sophisticated computer environment to support scientific inquiry, offers desktop assistance to ensure team members can get work done efficiently, and identifies new technology that will help the R&E team work more effectively.

The team includes nine highly qualified information technology professionals who provide the following services: application development, network and server support, desktop and helpdesk support, web and graphic design, database administration and support, and project management.



Selected 2010 Accomplishments

Data Center

In 2010, R&E's IT team set up a data center designed specifically to support research studies exclusively for KPSC. The new center supports collaboration through faster responses to queries pertaining to research. It allows much more efficient development of research applications.

Department Website

The team also completed development work for a new internal website to replace the existing R&E website, which had become outdated. The new site, which went live in early 2011, includes the following features:

- Search functionality to allow visitors to peruse current research studies and recent publications.
- Profiles of our scientists and their research interests.
- Detailed information on services R&E provides.
- Important forms and guidance to aid KPSC researchers through various phases of starting research projects.

Patient Stipends

Another key accomplishment was the creation of the Patient Stipend System, which routes stipend requests through an approval flow and then through the Kaiser Permanente payment system. It ensures data integrity and security as the stipend is being processed. Previously, this was handled through a slow and error-prone manual process.

Administrative Cost Dashboard

Additionally, the team developed the Administrative Cost Dashboard, which helps the administrative staff monitor and manage expenses related to the research projects. This tool reduces the work required to track the expenses related to projects and provides forecasting tools to manage expenses and avoid overruns.

Research Operations

The Research Operations unit is the newest group within the Department, founded in March 2010 with the hiring of an operations manager.

The unit's charge is to facilitate projects that improve automation, efficiency, and scalability within the research enterprise, collaborating with other business units to ensure smooth implementation of these projects. Specific areas of focus include addressing various training needs, working to create a career development ladder, and improving overall efforts regarding building safety.

The unit also includes two communications managers, hired in November 2010. Their primary task in 2011 will be to develop and implement a communication strategy that will raise the profile of the Department's research efforts within and outside of Kaiser Permanente.

Areas of responsibility for the communications team include: proactive planning for media and internal communications; media training; event management; Web and publication content management; annual report development; marketing collateral development; multimedia storytelling; and editorial support.



Selected 2010 Accomplishments

Surveys

Gathered feedback from scientists and staff to guide improvements in Department processes, operational issues, and staff morale. This included

- An assessment of the grant submissions process to identify areas of improvement.
- Surveys about staff development, including administrative grand rounds and the Department's orientation process.
- A suggestion box for the Department and regular feedback to staff about follow-up actions taken in response to their suggestions.



Emergency Response

Developed infrastructure to respond to crisis situations by

- Restarting the building emergency response team.
- Conducting a building evacuation drill in September.
- Coordinating CPR training for 75 Department staff.

Website Launch

Supported launch of the new Department website by

- Editing and creating content for key sections of the site.
- Developing a communication plan to publicize the launch of the site.

Department Identity

Promoted a stronger Department identity by developing branded items, including lanyards and shirts, for all team members.



Education Activities

R&E values the professional development of its staff by sponsoring monthly Journal Clubs, Department Seminars, and Administrative Grand Rounds designed to expose and educate our research cadre to current and relevant journal articles, accomplishments of scientific colleagues and federal regulations related to the conduct of research.

Journal Club

Since R&E researchers have various backgrounds, the Journal Club is organized around topics from each functional group to cover the broad interests of the scientific team. The Journal Club's purpose is to

- Provide a forum for a collective effort in keeping up with the literature.
- Share knowledge and promote the awareness of latest research findings.
- Improve critical literature appraisal skills.
- Discuss controversies.
- Inspire ideas and questions for future research.

The Journal Club covered a wide range of topics during 2010, including

- Soy food intake and breast cancer survival.
- Estimating race and ethnicity.
- Data collection in a multi-site project.
- Interpreting a genome-wide association study.
- Joint modeling of longitudinal and survival data.

Department Seminars

The monthly department seminars are a platform for knowledge sharing and discussion. The seminars are open to the KPSC community. Topics discussed in 2010 included

- The Cardiovascular Research Network.
- Self-reported vs. measured maternal pre-pregnancy and delivery anthropometrics.
- Prevention of lower genital tract cancer.
- Bariatric surgery registry.
- Surveillance of diabetes in children and youth: the SEARCH for Diabetes in Youth Study.



Administrative Grand Rounds

To ensure the transactions of R&E meet the highest professional standards, it is imperative that R&E staff understand the compliance processes governing the administrative management of extramural and intramural funding. The monthly Administrative Grand Rounds discuss an administrative research topic each month in detail. Topics for 2010 included

- National Institutes of Health Update.
- KPSC Research Data Warehouse Oracle Tables.
- Clinical Library Website Overview.
- Department of Clinical Analysis.
- Cost Allowability and Allocation.
- Research Compliance.
- Data Sharing.

Committees



Executive

The purpose of this committee is to provide the leadership, as well as the review and approval process, for the policies and procedures developed to support the business of research at KPSC. The committee is chaired by the SCPMG Director of Research and is composed of key administrative and research stakeholders.

Appointments and Promotions

This committee conducts a comprehensive analysis of the research job descriptions for scientists, revises them as necessary and develops the criteria for promotions within R&E.

Biospecimen

The purpose of this committee is to establish a research laboratory and biospecimen repository to support research efforts in KPSC.

Communication

This committee communicates the purpose and breadth of the research conducted within the KPSC region by developing a communication plan, identifying target audiences, creating talking points, and participating in the implementation of the communication plan.

Compliance

This committee reviews current compliance policies related to research. Committee members are also charged with revising and/or developing new policies to ensure KPSC is in compliance with all federal, state and local policies governing the conduct of research.

Data Quality

This committee documents the current data quality assessments used by the Department, prioritizes and develops active data quality assessments, and creates grant friendly text for data quality.

Recruiting

This committee standardizes the information being presented about R&E to job candidates in all functional units; establishes a standard framework for the interview process while maintaining flexibility to accommodate the needs of each functional unit; ensures that all functional units adhere to legal recruitment policies and guidelines; and streamlines the recruitment process.

Scientist Recruiting

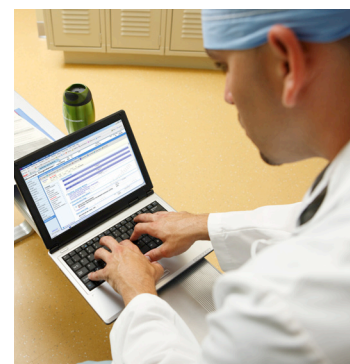
This committee develops job posting and advertising materials, screens candidates, and participates in all scientist recruitment efforts.

Technology Advisory

This committee evaluates the technology needs of the Department, assesses new technologies relevant to its mission, and proposes new software and hardware solutions to enhance quality and efficiency.

Web

This committee evaluates the current content and design of the Department website; proposes changes to expand the content and navigation of the website and manages website updates.



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Kaiser Permanente Southern California
100 South Los Robles, 3rd Floor
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