Information for Sponsors

Clinical trials research is a part of Kaiser Permanente's organizational mission to provide access to innovative new technologies and medicines to health plan members and to advance medical knowledge in the community at large.

The Southern California Permanente Medical Group (SCPMG) Clinical Trials Division under the Department of Research & Evaluation (R&E) has extensive experience collaborating with federal, academic, and industry sponsors. The program is part of a medical group that includes more than 6,600 physicians providing care to approximately 4.2 million members in clinic and hospital settings in Kaiser Permanente Southern California's 14 medical centers and 221 medical offices.

If you represent a sponsor interested in working with us, you will find most of the information you need to get started in this document. Please feel free to contact us at clinical.trials@kp.org with questions or requests for additional information.

Study Site Overview

Kaiser Permanente is the largest vertically integrated private health care delivery system in the United States, composed of three separate but closely connected organizations

- Kaiser Foundation Health Plan,
- Kaiser Foundation Hospitals, and
- The Permanente Medical Groups.

Nationwide, the Permanente Medical Groups provide prepaid medical care to more than nine million members of the Kaiser Permanente Medical Care Program. The Permanente Medical Groups have been conducting research into health care intervention and delivery since the 1950s.

The overarching goal of clinical trials research at Kaiser Permanente is to improve health and medical care through new knowledge.

Clinical Trials Division

The Clinical Trials Division focuses on research that advances clinical practice and to improve health outcomes. Our clinician investigators bring a perspective grounded in real-world clinical practice to their research. They seek to understand the impact of new drugs, biologics, and devices on patient health, and to answer important clinical questions.

More than 6,600 physicians provide care to approximately 4.2 million members in clinic and hospital settings in Kaiser Permanente Southern California's 14 medical centers and 221 medical offices.

The Clinical Trials Division oversees clinical trials research conducted in collaboration with industry, government agencies, and academic institutions. Our experience with clinical trials includes:

- Phase II to Phase IV drug and biologics,
- Pilot, Pivotal, and Post-market device trials, and
- Behavioral interventions.

Currently there are over 300 active studies in diverse therapeutic areas.

Clinician Investigators

The Clinical Trials Division also encourages our clinician investigators to incorporate their clinical expertise and questions into investigator-initiated clinical trials. These trials support Kaiser Permanente's commitment to innovation, quality, and service. They also advance clinical care and Kaiser Permanente's total health focus.

The division supports investigators as they conduct research, providing guidance on compliance with federal and state regulations as well as institutional policies and procedures.

In general, Kaiser Permanente Southern California conducts clinical trials to:

- ensure that clinician investigators offer "cutting edge" medicine and innovative products,
- provide patients access to promising therapies,
- advance medical knowledge, and
- ensure results are applicable to diverse membership.

First Steps: Approaching a New Clinical Trial

Sponsors are may to contact Clinical Trials Division directly for new clinical trial protocol inquiries to facilitate the pairing of sponsor and contract research organization (CRO) with qualified clinician investigators. Additionally, this central routing ensures timely response and follow-up on the inquiry.

The Clinical Trials Division will execute a confidentiality agreement (CDA) with the sponsor. If there is a pre-signed/master CDA with the sponsor, this step can be excluded. On average, a new CDA can be turned around in 24 to 48 hours.

The Clinical Trials Division then reviews the synopsis and protocol to assess fit and feasibility and to identify possible clinician investigators and study sites within the organization. When a Principal Investigator is identified, a representative from the Clinical Trials Division will forward the contact information and other requested information to the sponsor.

Acceptance Criteria for New Protocol

Determinants of accepting a clinical trial protocol are:

- having an identified potential Principal Investigator in therapeutic area,
- physician interest/preferences,
- feasibility within Kaiser Permanente and/or site, and
- value and risk to patients.

To proceed, a PI is required to obtain the following additional approvals from:

- Area Research Chair, Chief of Service and Department Administrator
- Clinical Trial Oversight Board (CTOB): evaluates overall feasibility, scientific validity, and appropriate fit with KPSC organization values
- Kaiser Permanente Southern California Institutional Review Board (KPSC IRB)

All clinical trials conducted in whole or in part in KPSC are required to be submitted to the local Kaiser Permanente Southern California Institutional Review Board (KPSC IRB) for review and approval, which is scheduled every 3rd Tuesday of the month. For more information, refer to the KPSC IRB Website at http://irb.kp-scalresearch.org/index.html.

PI and Study Site Staff Training

Clinical Trials Division requires clinician investigators and study site staff to have the following training completed prior to their involvement in a clinical trial:

- Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP) for clinical trials
- Collaborative Institutional Training Initiative (CITI) Conflict of Interest
- HIPAA Privacy Rule and Research Training
- KPSC-IRB SOP-502, Principal Investigator Reportable Event and Incident Requirements
- Investigational Drug Management Training, as applicable
- Department of Transportation (DOT), as applicable

Budgets, Contracts and Invoicing

Through Research Business & Contract Operations, we provide centralized budget and contracting to help

support and manage sponsored clinical trials within the Southern California Permanente Medical Group (SCPMG). Each study protocol is assigned to a Contracts and Grants Administrator from Sponsored Programs Administration, who is responsible for that specific protocol. The assigned administrator is responsible for all aspects of budget development and contract negotiation on behalf of the PI and SCPMG.

In reviewing the sponsor's protocol and study flow chart (schedule of events), the assigned administrator will work with the PI and/or designee:

- To confirm all study required procedures/ activities;
- To identify study-specific procedures/activities from standard of care;
- To determine his/her effort to oversee the clinical trial; and
- To obtain assurance of their ability to perform the identified required services.

The assigned Contracts and Grants Administrator prepares a cost estimate for the study that will include direct research costs based on the protocol-related requirements, and start-up fee to cover the administrative costs associated with KPSC IRB review of the protocol, Sponsored Project Administration negotiation of the contract agreement, medical center preparation and set-up.

Once the protocol procedures and proposed internal costs are finalized, the Contracts and Grants Administrator will negotiate with the sponsor for all costs of the incremental research activity. Contract approval will be finalized when the protocol has been approved by KPSC IRB, and the contract and budget terms have been successfully negotiated through the Contracts and Grants Administrator.

Sponsored Project Administration will forward copies of the signed contract and final cost information to the PI, the KPSC IRB, and Research Business & Contract Operations. Research Business & Contract Operations expects to review, complete and approve all negotiations with the sponsor within 60 business days.

Invoices will be generated promptly based on completed work and contract stipulations negotiated with the sponsor.

Site Management and Oversight

KPSC PIs and study site staff are required to conduct clinical trials in compliance with the KPSC IRB approved study plan, applicable federal and state regulations, as well as institutional policies and procedures that include the KPSC Clinical Trial Standard Operating Procedures.

Clinical Trials Divisions offers the following services:

- Providing orientation and training for clinician investigators and site staff.
- Assisting with site feasibility assessment for potential studies
- Collaborating with Research Business & Contract Operations in budget review for staffing
- Recruiting and hiring study site staff to support studies
- Developing workflow processes for successful participant recruitment, and study implementation and management
- Assisting with Sponsor communication and monitoring
- Guiding clinician investigator and staff to ensure compliance with applicable regulations, policies, and procedures including the protection of the safety, rights, and welfare of research participants

KPSC IRB Submissions and Regulatory Management

Clinical Trial Division provides regulatory support and consultations by

- assisting with KPSC IRB electronic submissions using integrated Research Information System (iRIS®), which has been certified to meet the requirement of 21 CFR Part 11
- providing consultation on applicable federal and state regulations, and institutional policies and procedures; and
- assisting with quality improvement initiatives through standard operating procedure (SOP) review and development.

Source Documentation and Study Data Management

Kaiser Permanente HealthConnect® is the electronic medical record (Epic-based) utilized throughout the KPSC that has been certified to meet the requirements of 21 CFR Part 11. The system is the medical record for all inpatient, ambulatory, and Kaiser Permanente services, including laboratory, pharmacy, and radiology, and hence is the source data for clinical trials conducted within these facilities.

Subject-specific hard-copy study charts and hard-copy worksheets may be used to help organize the source documents for studies in which a large amount of data or when complicated information is collected.

Investigational Drug and Pharmacy Services

Each KPSC medical center has a fully staffed pharmacy on the premises that may be engaged as required by the study to conduct a clinical trial that involves investigational drug. The involvement of a KPSC pharmacy in a clinical trial must be agreed upon by both the sponsor and the PI. The PI will interface directly with the local pharmacy operations based on protocol needs, which may include secure space to receive, inventory (maintain accountability logs), and dispense the investigational drug.

Specimen Collection and Shipping

KPSC PIs and study site staff are experienced with working with a variety of central laboratories. Those directly involved in the packing and shipping of specimens are required to have current certification for the Department of Transportation (DOT) training provided by KPSC. In general, clinical trials conducted at KPSC utilize licensed phlebotomists within the Southern California Permanente Medical Group Regional Reference Laboratories.

In cases where a clinical trial requires the involvement of a local laboratory, KPSC has more than 120 licensed and registered laboratories (inpatient and ambulatory) in the Kaiser Permanente Southern California system. They are linked together under the Southern California Permanente Medical Group Regional Reference Laboratories. The laboratories are fully staffed, well equipped and perform a wide range of analyses including pharmacogenomics and pharmacokinetic tests.

Study Monitoring and Auditing

KPSC PIs and study site staff understand the responsibility of sponsor's to monitor the study and will work with sponsors to facilitate the process.
Since KPSC utilizes the Kaiser Permanente HealthConnect®, monitors and auditors acting under the confidentiality and contractual agreement of the clinical trial are provided "Read Only" access to view source documentation for enrolled subjects.

Internal Quality and Compliance Program

Clinical Trials Divisions has a quality and compliance oversight program that offers the following services to KPSC PIs and study site staff:

- Reviewing for quality assurance and compliance to address and prevent noncompliance
- Assisting with external audit (e.g. FDA or cooperative group) preparation.

Record Retention Practices

To comply with federal and state requirements applicable to clinical trials, KPSC is committed in retaining study records as required by regulations and as stated in the protocol and/or the clinical trial agreement. When multiple retention periods apply for a study, the longest period (or most stringent standard) will be followed. Unless otherwise specified in the clinical trial agreement, study records are retained no longer than 10 years after the study is closed with the IRB.

In general, archiving of study records are done within one year after IRB closure with approval from sponsor by sending the records to a KPSC-approved long-term storage facility. Clinical Trials Division currently employs Iron Mountain Retention Facility for long-term record retention.

Contact Us

If you have questions or need additional information, please contact:
Hai Linh T. Kerrigan, PharmD, Division Research Administrator at clinical.trials@kp.org