KAISER PERMANENTE®
Institute for Health Research

The Institute for Health Research Clinical Trials Program (IHR-CTP) team is designed to conduct clinical trials and provide support for Principal Investigators.

IHR-CTP team provides the following:

Clinical Trial Set Up

- Feasibility assessment
- Contracting
- Budget and Invoicing
- Study site set-up

IRB Compliance

- IRB application, development of consent and HIPAA forms
- IRB amendments and continuing reviews
- Notification of IRB communications

Data Management

- Identification of appropriate data management systems
- Development of data management plan
- Development of source documents
- Data acquisition and input
- Prepares Investigational New Drug (IND) report for sign off
- Long term storage of trials data

Participant Recruitment and Management

- Identification of eligible participants
- Participant screening
- Enrollment and informed consent
- Coordinate participant study visits
- Participant tracking and recording of outcomes

Study drug monitoring and safety

- Receive and maintain study drug
- Draft study drug orders as applicable to the study (i.e. beacon orders for oncology)

Adherence to sponsor protocols and requirements

- Prepare documents for, supports and attends sponsor monitoring activities

Study site close out

Ancillary service relationships

- Set up support from radiology, lab, pharmacy, etc. as necessary
- Maintain staff education and certification for the study