KAISER PERMANENTE®
Institute for Health Research

Principal Investigator Responsibilities

A principal investigator is ultimately responsibility for all activities associated with the conduct of a research study including compliance federal, state and local laws, institutional policies and ethical principles. Much of the PI responsibilities are to review and approve the work of the CT team.

CPMG physicians must get approval from their Clinical Department Chief and Regional Medical Director. See CPMG Approval for Research Activities

Required Trainings

- CITI - online training for ALL involved in human subjects research. (must be complete to participate in any research activities)
- IRBnet training- necessary to review and sign-off on all regulatory documents. (IRB provides a document to review)
- Study specific trainings (ad hoc from sponsor)

Required Documents

- Up to date and signed CV
- Completed 1572 form (if FDA regulated study)

Document Review and Sign-off

- All IRB documents – required to start a CT (IRBnet)
- Ongoing sign off on all adverse event documents according to deadlines (IRBnet)
- IND safety reports (paper)
- Notifications of change of risk – (paper)
- Delegation logs (paper)
- Participant orders (i.e. Beacon, drug builds)
- Electronic case report forms

Facilitate participant recruitment

- Keep physicians within the practice informed and up to date regarding trial activities
- Notify coordinator of eligible patients