HAWAIʻI PACIFIC HEALTH | KAPIʻOLANI PALI MOMI STRAUB WILCOX

Principal Investigator Responsibilities

The Principal Investigator (PI) is responsible for personally conducting or supervising the conduct of human subject research and for protecting the rights, safety, and welfare of the subjects enrolled in the research. The PI must ensure that all human subject research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies and requirements and determinations of the reviewing Institutional Review Board (IRB).

Who may serve as Principal Investigator?

1. Medical Staff of Hawai'i Pacific Health who are credentialed at the facility where the research will be conducted.

2. Physician residents and fellows practicing under the supervision of attending medical staff who will serve as the PI.

3. Allied Health Professionals (i.e. nurses, pharmacists, social workers, therapists, etc.) may serve as PI on research that does not include dispensing of study drug and/or research that includes medical procedures as part of the study.

How do I initiate research at HPH?

1. Principal Investigators should submit:
    a. Research protocol and
    b. Research data collection tool

2. PIs and each research team member needs to submit/complete (as applicable):
    a. Current medical license
    b. Current Curriculum Vitae (CV) – signed and dated
    c. Completion of HPH CITI training – Human Subjects Protection
    d. Completion of HPH CITI training – Good Clinical Practice (GCP) (For those PIs conducting research that involves interaction with human subjects).
    e. Completion of HPH financial conflict of interest training
    f. Completion of HPH Financial Conflict of Interest disclosure form

PIs must maintain a study file of Human Subject Research (HSR) documents for each study:

1. The PI must maintain a file of HSR documents for each study submitted and approved with the HPHRI (Hawai'i Pacific Health Research Institute). The file must include, at a minimum, the following items (as applicable):

    a. A copy of the protocol and all subsequent approved protocol revisions.
    b. Original of each consent form signed by each participant enrolled in the research study.
    c. A copy of all data derived from the study (case report forms, computer data, adverse event reports, and research progress reports submitted for IRB purposes).
    d. All IRB approvals, if applicable.

PIs must appoint, train and supervise research team members

1. The PI is responsible for appointing study team members. All study team members must complete related HPH research training requirements and must also:

    a. Have read the protocol and subsequent protocol revisions.
    b. Have completed required HPH research training;
    c. Have experience and/or training in the responsibilities assigned to them by the PI.

Additional HPH requirements of Principal Investigators and other research team members:

1. All research requires review by the HPH Scientific Review Committee (SRC) unless the study has otherwise been peer reviewed. HPHRI will facilitate this review on your behalf.

2. The PI will be required to respond to and resolve all questions posed by the SRC in order to move the study forward for review.

3. All research conducted at HPH require facility Feasibility and Administrative Review and approval prior to IRB submission. HPHRI will facilitate these reviews/approvals on your behalf.

4. All research conducted at HPH requires a financial review of projected costs to conduct the study. If a study demonstrates uncovered costs it will require a plan for cost coverage by the PI or the study will not move forward for review.

5. If your research involves human subjects it will require HPH Institutional Review Board (IRB) approval or determination of exemption from IRB review by the Institutional Official (this will be facilitated by HPHRI) *prior to the start of any aspect* of the research study. HPHRI currently utilizes the Western Institutional Review Board (WIRB) as our local IRB.

6. Attend Sponsor and Coordinator meetings, and participate in FDA inspections, sponsor monitoring visits, sponsor audits and other required study meetings.

ONLY when these steps are acknowledged and completed can a research study begin at HPH.