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Guidance for Investigators Conducting Clinical Trials with Hawai'i Pacific Health Research Institute

This guidance is intended to clarify for investigators the FDA's expectations concerning the investigator's responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees, colleagues of the investigator, or other third parties, and (2) to protect the rights, safety, and welfare of study subjects.

1) Supervision of the Conduct of a Clinical investigation

An investigator's responsibilities in conducting clinical investigations of ***drugs or biologics*** are found in 21 CFR Part 312. Many of these responsibilities are included in the required investigator's signed statement, Form FDA-1572 (see attachment A).

An investigator's responsibilities in conducting clinical investigations of a medical device are provided in 21 CFR 812, including the requirement that there be a signed agreement between the investigator and sponsor.

Investigators who conduct clinical investigations commit themselves to supervise all testing of the drug or device involving human subjects. It is a common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties. When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated.

The investigator should have sufficient time to properly conduct and supervise the clinical trial. Supervision and oversight should be provided even for individuals who are highly qualified and experienced.

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Some of the time commitments, during the course of a clinical trial, are:

- Providing a current copy of your CV and current medical license. Your CV should be updated, to include the institution in which you are conducting the research.
- Completing the CITI training modules, before submission of a study to the IRB, and renewing that training every two years.
- Working with the Hawai'i Pacific Health Research Institute regulatory coordinator in providing information for the IRB application, before the study can be submitted to the IRB.
- Signing the investigator signature page of each protocol, the FDA Form 1572, IND safety report memos, quarterly and annual IRB reports and many other documents, throughout the course of the study.
    - It may be helpful for you to make a specific "in box" for research, where the coordinator can put your research documents that need signing. When you are finished, the coordinator can pick up the signed documents, from the "in box".
- Attending the Investigator's meeting, which is held before the start of each study. If you are unable to attend, the sponsor may arrange a webcast which you can attend.
- Attending the Site Initiation Visit (usually 1-2 hours), which is held at your site, before starting study enrollment.
- Holding routine, documented meetings with staff to review trial progress, adverse events, and an update on any changes to the protocol or other procedures.
- Attending routine meetings with the sponsor's monitors- these will occur at least every 6 weeks, depending on your enrollment activity.

- Insuring subject safety and reporting (within 24 hours) all Serious Adverse Events.
- Timely (within 7-10 days) signing of all lab results, research EKG's, and post-visit letters of the monitor's findings.
- Correcting problems identified by study personnel or outside monitors for auditors.
- Timely (within 7-10 days) sign off on data queries and discrepancies identified by the study monitor.
- Meeting with the sponsor's monitors at the close out visit, for each study.

2) Protecting the Rights, Safety, and Welfare of Study Subjects

Investigators are responsible for protecting the rights, safety, and welfare of subjects under their care during a clinical trial (21 CFR 312.60) and 812.100). This responsibility includes:

- Providing reasonable medical care for study subjects for medical problems arising during participation in the trial that are, or could be, related to the study intervention.
- Providing reasonable access to needed medical care, either by the investigator or by another identified, qualified individual (e.g., when the investigator is unavailable, when specialized care is needed, etc.).
- Adhering to the protocol so that study subjects are not exposed to unreasonable risks.