PI Responsibilities

The Department of Health and Human Services and the US Food and Drug Administration created a guidance document on Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects. Investigators are strongly encouraged to read the guidance prior to initiating a research study involving humans.

PI responsibilities include:

- Protect the rights, safety, and welfare of research subjects.
- Abide by federal and state regulations and ICH guidelines for GCP governing human research and informed consent.
- Obtain CHA IRB approval prior to initiating human research and conduct a research study according to the IRB-approved protocol.
    - Understand, comply with, and execute the data and safety monitoring plan in the approved protocol.
    - Ensure the informed consent process is free from coercion or undue influence, has been voluntarily obtained, has been properly documented (45 CFR 46.116; 45 CFR 46.117), and is obtained prior to the initiation of any study-related procedures;
    - Ensure subject safety.
    - Ensure subject privacy and confidentiality.
    - Communicate new information, including safety information, developed during the course of a study that may relate to a subject's willingness to continue participation in a study.
    - When drugs, biological products, and devices are being investigated or used, they are managed and controlled as required by institutional policy and, when applicable, FDA regulations 21 CRF 312 and 21 CFR 812;
    - Be familiar with the proper use of an investigational product, as described in the protocol, in the current Investigator's Brochure, in a product information guide, and in other information sources provided by the sponsor, as applicable.
- Ensure all research team members are qualified by education, training, orientation to the study protocol, and experience to perform their designated research responsibilities. Provide ongoing oversight and supervision of research team members.
- Consider, disclose, and manage actual or perceived conflicts of interests in accordance with federal and state regulations and institutional policy.
- Maintain integrity of study records (*e.g.,* legible, accurate, complete, contemporaneous).
- If CHA IRB approval should lapse, research procedures (including subject recruitment and enrollment, study procedures on enrolled subjects, review of medical or research records, collection of specimens, analysis of data, *etc*.,) are not conducted until the CHA IRB re-approves the research

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or until special permission is obtained from the CHA IRB in writing allowing previously enrolled subjects to continue in the study because it is in their best medical interests to do so.

- Keeping certain records as required by the DHHS and/or FDA regulations for at least 3 years after completion of the study (45 CFR 46.115(b)). NOTE: CHA policy requires study records be retained for 7 years after the completion of the study;

PIs are expected to submit the following to the IRB:

- Written request for clarification if s/he is in question whether a project constitutes research or QI.
- Each new study application (*e.g.,* exempt, expedited, convened IRB review); research may not commence until written IRB approval is provided.
- Request for modification to a previously approved or exempt study, including changes among the research team. A change may not be initiated until IRB review occurs and written IRB approval is provided, except when necessary to eliminate apparent immediate hazards to a subject (45 CFR 46.103(b)(4).
- A subject complaint.
- Continuing review applications per institutional policy (45 CFR 46.103(b)(4), 45 CFR 46.109(e), 45 CFR 46.115(a)(1)).
- Any internal or external audit or other monitoring findings.
- Notification of any change in study status of a study (*e.g.,* closed to enrollment, termination).
- SAE and/or unanticipated problem reports (45 CFR 46.103(b)(5)).
- Promptly report serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB (45 CFR 46.103(b)(5)).
- Notification upon learning that a research subject has become incarcerated while participating in a study. All research interactions and involvement with the incarcerated participant, as well as obtaining identifiable private information about, must stop until the requirements of 45 CFR 46 Subpart C (and 21 CFR 56 , if applicable) have been satisfied.
- Final reports and requests for termination (45 CFR 46.103(b)(4), 45 CFR 46.115(a)(1)).