CAPE FEAR VALLEY HEALTH	**IRB Guidance:** Investigator Responsibilities

This document is to outline the responsibilities assumed by a Principal Investigator when applying to conduct human subject research activities at Cape Fear Valley Health System. The Faculty Advisor assumes the role of Principal Investigator and its responsibilities when working with Residents and Students.

Introduction

When applying for approval to conduct human subject research at Cape Fear Valley Health System (CFVHS) each application must have an IRB Investigator Agreement attached and signed by the Principal Investigator (PI) who agrees to assume the responsibilities outline in the agreement. The responsibilities are standard across applications.

When conducting multi-site research for which the investigator requests a reliance arrangement, investigator responsibilities will change depending on whether CFVHS will assume responsibility as the reviewing IRB or whether the IRB oversight is deferred to another institution's IRB or Central IRB.

Principal Investigator and Faculty Advisor Responsibilities

At the time of initial submission, an eligible PI or Faculty Advisor must sign the application or IRB Investigator Agreement. The PI agrees to assume these responsibilities while the protocol remains active and approved for human subject research activities.

When signing, the Faculty Advisor agrees to provide oversight for the conduct of the research and assumes the same Principal Investigator Responsibilities. The Faculty Advisor is expected to support the resident/student researcher with submissions to the IRB. This includes support of the development of protocol materials, review of materials prior to submission, and preparing responses during the review process.

Principal Investigators

The following are the PI responsibilities and are not all inclusive:

1. Assure that all personnel listed on the research protocol have completed the human subjects research training.
2. Assure that all covered individuals listed as research personnel on non-exempt protocols have submitted a Financial Interest Disclosure.
3. Submit protocols for IRB review and approval of proposed research activities prior to commencing the research activities.
4. Employ sound study design in accordance with standards of the PI's discipline.
5. Assure that adequate time and resources are present before conducting a research project to assure participant protections.
6. Maintain appropriate oversight of each research project, as well as research staff, and appropriately delegate research responsibilities and functions.
7. Ensure that the research is conducted according to the protocol, any signed agreements, in compliance with all applicable laws and regulations and organizational policies and procedures with the highest of ethical standards.

8. Submit for review and approval all proposed protocol and consent form changes prior to implementing the changes in the protocol except where necessary to eliminate apparent immediate hazards to human subjects.
9. Obtain legally effective informed consent from subjects prior to commencement of research activities unless the requirement is waived by the IRB.
10. Ensure the rights, safety and welfare of the research subjects are upheld and protected.
11. Follow reporting requirements for problems that require prompt reporting.
12. Submit requested data at specified times for continuing review of ongoing research activities.
13. Upon completion of a project, honor all commitments that were agreed to as part of the approved research, e.g., providing information about the project results to research subjects or honoring commitments for reimbursements to subjects.
14. Upon completion of a project, submit a Closure Report to the IRB.
15. Disclose all conflicts of interest.
16. Retain records as required by the regulations, the sponsoring entity and local policy for the appropriate time period.
17. When PI is the lead researcher for a multi-site project, applications must include information about the management of information that is relevant to the protection of research participants, e.g., interim results; protocol modifications; how unanticipated problems involving risks to participants or other unanticipated problems will be managed.; how communication of unanticipated problems to all sites will occur; how protocol modifications will be managed; is there a formal agreement in place delineating each site's roles and responsibilities.
18. If the PI holds an IND/IDE, adhere to sponsor responsibilities in addition to investigator responsibilities as per 21 CFR Parts 312/812.
19. If appropriate, assure that applicable clinical trials and NIH sponsored clinical trials are registered on the governmental database at ClinicalTrials.gov. for more information.
20. Address research participant's concerns, complaints, or requests for information.

Faculty Advisor Principal Investigators for Resident/Medical Student-led Research

CFVHS requires all research to be conducted under the guidance of a qualified Principal Investigator. As a teaching institution, residents and medical students will be engaged in conducting research as an integral part of their educational experience. Faculty who assume PI responsibility for resident/medical student-led research involving human subjects must be willing to provide oversight to the research activities and assume full responsibility for the conduct of the research. The Faculty PI must be actively involved in the research, from protocol design to data analysis and report preparation. In many cases, it may be the student's first experience with formal research. The success of the student's experience will be measured not only in the outcome of their projects, but also in what they learn from the faculty sponsor. These experiences will help form their perception of scientific research, and in some cases, determine whether a career in academic research is right for them. The following are the Faculty PI responsibilities and are not all inclusive:

1. Advise the resident/medical student on the selection of a topic, the content and preparation of their research proposal. Understand the research hypothesis, goals, and methodology. Guide and interact with the resident/medical student throughout the research project.
2. Assist the resident/medical student with the preparation of the IRB application. As the PI on the project, submit the application to the IRB. Ensure the resident/medical student obtains all necessary approvals (i.e., IRB) before initiating the project, implementing any changes in the research activities, and continuing the research activities after the approval period has expired.
3. Assume full oversight of the IRB protocol and ongoing when the resident/medical student leaves the institution prior to completing the research protocol.
4. Ensure that the resident/medical student is provided with, or has access to, information on CFVHS policies relating to administration of their protocol.
5. Assure the resident/medical student understands the underlying ethical principles for conducting research with human subjects and the applicable research regulations and local policies and procedures. Stay abreast of the status of the protocol and ensure on-going compliance with federal regulations and institutional policies and procedures relating to human subjects research and IRB required reporting.
6. Advise and assist resident/medical student with the preparation of poster presentations and papers, as applicable.
7. Ensure that all project documents and data are archived at the end of the project in accordance with federal, state, and local policy and regulations.
8. Be available to the resident/medical student during the active research period.

Principal Investigator Responsibilities for Collaborative and Multi-Site Research

Collaborative and multi-site research may call for a reliance arrangement in which the CFVHS IRB will serve as the single IRB (IRB of Record) or defers oversight to another IRB. With a reliance arrangement, additional investigator responsibilities are agreed to by the collaborating investigators. Below are the responsibilities for the CFVHS and Site investigators depending on the reliance arrangement in place.

1. **Investigator Responsibilities when CFVHS IRB defers review to another IRB**
   When a Reliance Request is initiated, the CFVHS Principal Investigator agrees to assume responsibility for the conduct of the research locally and agrees to adhere to the requirements of the reviewing IRB. The reviewing IRB may require additional responsibilities of the CFVHS investigator.

   The CFVHS Investigator is responsible for the following, this list is not all inclusive:
   a. Submitting a reliance request to the CFVHS IRB to initiate the reliance review and approval process for CFVHS IRB to relay on an external IRB.
   b. Provide or facilitate access to protocol materials used by the relied upon site to secure approval.
   c. Provide information to CFVHS IRB and federal regulator as requested during the protocol review and approval process and throughout the conduct of the research while CFVHS is relying on another IRB or record.

d. Conduct the research in accordance with the approved protocol and using the approved materials.
e. Ensure that the lead PI has secured approval for any changes prior to implementation of any changes to the research activities locally.
f. Fulfill obligations as a site PI per the terms of the reliance arrangement.
g. Ensure local compliance with the IRB approved protocol and with CFVHS institutional requirements listed under ***"Principal Investigators"*** listed above.

Adapted from University of Oregon's "Investigator Responsibilities Guidance" document and University of Texas at Austin's "IRB Policies and Procedures Manual.