CAPE FEAR VALLEY HEALTH SYSTEM
Policy – Procedure

Title: Human Research Protection Program Compliance	**Effective Date:** 10/19/2024

Purpose: In order to promote ethical human research and facilitate compliance with applicable laws, regulations and policies, this Policy established the framework for Cape Fear Valley Health System's Human Research Protection Program compliance and provides information on how to report allegations of noncompliance in human subjects research.

Audience: All members of the Cape Fear Valley Health System community.

Departments: All Hospital Departments, Medical/AHP Staff, All Staff, Agents

Keywords: Research, Human Subject, Compliance, Research Compliance, Institutional Review Board (IRB)

Definitions:
Human Subject : A living individual about whom an investigator conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR 46.102€; or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control, who may be wither a healthy human or patient (21 CFR 50.3(g).

Human Subject Research: Research: Research, as defined by 45 CFR 46.102(l) or clinical investigation, as defined by 21 CFR 50(c).

Institutional Review Board (IRB): Committee authorized to review, approve, require modifications in (to secure approval) or disapprove all Human Subject Research at CFVHS in accordance with all federal, state and local regulatory requirements as well as institutional policies and procedures.

Policy:
Cape Fear Valley Health System (CFVHS) is committed to protecting the rights and welfare of human research participants and ensuring compliance with all applicable ethical and legal requirements.

Procedural Guidelines:
1. General Information
   CFVHS is committed to protection rights and welfare of participants in human subject research. CFVHS has established a Human Research Protection Program (HRPP) to comply with the ethical and legal requirements for the conduct and oversight of human subjects research. CFVHS's Institutional Review Board Office (IRB Office), which is responsible for

supporting the administration of the IRB, works with the IRB and other CFVHS divisions to ensure compliance with the HRPP.

2. Reporting Concerns

Any person having concerns about the conduct of human subjects research at CFVHS is strongly encouraged to report incidents involving perceived noncompliance through one of the following mechanisms:

- Directly contacting the IRB Office at irb@capefearvalley.com
- Use of the **Human Subject Research Concerns or Complaints Form** located on the Cape Fear Vally Health website.
- Investigators and research staff should self-report non-compliance using the appropriate IRB Reportable Event Submission.

Anyone within the CFVHS who receives a concern or complaint is encouraged to contact the IRB Office or provide the above information to the individual with the concern or complaint.

All human subject research concerns and complaints are taken very seriously. The information provide will be kept as confidential as possible. However, we may need to share this information with others to follow-up with a concern or complaint. The Human Research Protection Program and the Institutional Review Board adhere to Cape Fear Valley Health System's Whistleblower Policy, which prohibits retaliation against individuals who, in good faith, report alleged noncompliance.

The IRB Office and IRB have the responsibility of investigating allegations of noncompliance in human subjects research and imposing corrective actions as needed. In addition to audits conducted by the IRB Office in response to reports of alleged or perceived noncompliance, the IRB Office also conducts routine post-approval monitoring of human subjects research at CFVHS.

The Institutional Official (IO) may impose additional corrective actions up to and including barring individuals from conducting humans subjects research at CFVHS if the IO conduces such actions are required to maintain compliance the HRPP.

3. Additional Components of the Human Research Protection Program

Legal Services provide the IRB and other components of the HRPP with counsel on an as needed basis, primarily on matters related to state laws, cooperative agreements, noncompliance, conflicts of interest, and contractual issues in human subjects research.

Corporate Compliance partners with and educates the research community with response to appropriate practices related to the institution regarding the conduct of research and corrects noncompliance when applicable.

Financial Office ensures all terms of the award are in compliance with Institutional policies.

Risk Management provides internal and external monitoring, which is designed to assess compliance and safety in human subjects research.

Related Documents/Policies:

- Human Research Protection Program Plan
- IRB Authority and Responsibilities
- CFVHS-IRB Administrative Standard Operating Procedure - 090: Complaints and Allegations of Non-Compliance

References:

- 45 CFR 46
- 21 CFR 50