CAPE FEAR VALLEY HEALTH	**IRB Guidance:** Human Subjects Research Protection Training Requirements

Purpose: The purpose of CFVHS Human Subject Research Protections (HSRP) training is to promote responsible conduct in research, scientific integrity, and public duty.

Requirements:

All individuals conducting research activities such as, design, conduct, or analysis of human subjects research, or accessing identifiable information covered under HIPAA regulations is required to complete HSRP training via the National Drug Abuse Treatment Clinical Trials Network's (NADT): Good Clinical Practice Course.

Additional training may be required for individuals when conducting research funded by certain federal agencies (e.g., Department of Defense, Department of Navy, NSF, and NIH). It is the Principal Investigator's (PI) responsibilities to know and obtain the required training. The IRB Office can assist researchers in locating additional training courses.

Requirements:

1. Principal Investigators (PIs), Faculty/Staff Advisors, Staff, Residents and other research staff are required to obtain certification in human subjects research protections (HSRP) via the National Drug Abuse Treatment Clinical Trials Network's (NDAT): Good Clinical Practice prior to submitting your application to the IRB.
2. The training can be found at https://gcp.nidatraining.org/.
3. Follow the instructions and when you have completed the course you will receive access to your completion certificate.
4. The training consists of twelve modules and requires a score of at least 80% to receive your certification.
5. Certifications are valid for 3 years before renewal is required.
6. Remember to save your certification as you will need to submit a copy with each IRB submission.

Principal Investigator Responsibilities:

For each new submission received by the IRB, the IRB Office will verify that training requirements of all project ream members (including volunteers, interns, and student workers) have been met. If they have not been met, the IRB Office will return the submission to the research team. You may re-submit for review only after all training requirements have been met or after removing individuals who have not met requirements from your project team as appropriate.

Subsequent to a new protocol application and subsequent submissions, for minimal risk and greater than minimal risk research projects it is the responsibility of the PI to verify and maintain a record of the training of all project team members. The IRB will continue to monitor the currency of training for all PIs for all submission types. Currency of training will be monitored by the IRB Office for all project team members at the time of Continuing Progress Review. For all external collaborators for who there is an Individual Investigator Agreement (IIA) or an external IRB Authorization Agreement (IAA) the CFVHS IRB with CFVHS as the IRB of Record, the currency of training will be the responsibility of the CFVHS Principal Investigator.