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

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 are required to complete certification training through CITI Training **prior** to submitting proposals to the IRB for determination or approval.

Additional training may be required for individuals when conducting research funded by certain federal agencies (e.g., Food and Drug Administration, 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.

If you are conducting Non-Human Subject Research (NHSR) you do not need to complete human research protection training. It is highly recommended you take the Biomedical Responsible Conduct in Research course.

This section describes the training requirements required by the CFVHS IRB. You may have additional training required by other federal, state, or institutional policies.

1. **All** CFVHS personnel conducting human subjects research must complete the following two courses hosted by CITI Programs:
    a. **CITI Health Information Privacy and Security for Investigators**, and
    b. **Biomedical Responsible Conduct of Research.**
2. CFVHS personnel listed on a human subjects research project must complete a Human Subjects Protections Training course hosted on the CITI Programs:
    a. Completion one of the following courses which best applies to the research, or your role satisfy this requirement:
        i. **Group 1: Resident & Trainee**
        This is a basic course for research activities that are "minimal risk" or less, such as research projects qualifying for Exempt Review (e.g., most survey, medical records, benign behavioral intervention research projects).
        ii. **Group 2: Biomedical Research**
        Biomedical involves research activities that are minimal risk or greater such as projects meeting the requirements for Non-Exempt Review except for FDA regulated clinical trials/investigations (e.g., interventional research and some clinical research projects projects).
        iii. **Group 3: Clinical Trial Research**
        This group is for researchers conducting FDA regulated clinical trials/investigations.
        iv. **Group 4: IRB Members**
        This group combines both biomedical and social behavioral research topics in addition to administrative topics. Only IRB members are required to complete this course.
        v. **Group 5: Data or Specimens Only Research**

This course is specifically designed for researcher conducting only data or specimen research.

   b. If expired, completion of the associated refresher course is required. After three cycles of refresher training, the basic course must be completed.

3. In addition to the above, CFVHS personnel listed on clinical trial studies or federally funded NIH research as Principal Investigator or those involved in identifying/recruiting subjects, obtaining informed consent, or interacting and intervening with subjects must complete:
   a. **CITI Good Clinical Practice Course**.
   b. **If expired, completion of the associated refresher course is required**. After three cycles of refresher training, the basic course must be completed.
4. In addition to the above, Principal Investigators on sponsored or funded Non-Exempt human subjects research must complete the **Conflict of Interest** (COI) training hosted by CITI Programs.
5. Non-affiliated researchers and project personnel listed on a human research project must complete a similar human research protections training program or one of the CFVHS training programs listed above.

Instructions:

1. Go to CITI Program home page at CITI Program or Research, Ethics, and Compliance Training | CITI Program.
   a. If you already have an account with CITI Programs, you will need to affiliate your account with Cape Fear Valley Health System to ensure your current training modules will not need to be repeated.
2. For detailed instructs please see Getting Started for step-by-step instructions for registration, institutional affiliation and courses available.
3. Make sure you choose Cape Fear Valley Health System as the institution.
4. Complete your personal information and use your Cape Fear Valley email address. You may select a secondary email address if you wish to.
5. When selecting courses, you will be presented with a series of questions or options to enable you to enroll in the courses appropriate to your research or your role in the research as listed above under “Requirements”.
   - **Question 1: Human Subjects Research** – select based on requirements listed above.
   - **Question 2: Good Clinical Practice (GCP)** – select if you are conducting clinical trials research.
   - **Question 3: Health Information Privacy & Security** – select:
     - Information for Investigators: if you are conducting clinical trials research.
     - Information for Clinicians: all other users.
   - **Question 4: Financial Conflicts of Interest (FCOI)** - if you are conducting clinical trials research or funded research.
   - **Question 5: Responsible Conduct of Research** – all users must complete this course.
6. Complete required courses.

7. A score of at least 80% is required to receive your certification.
8. Certifications are valid for 3 years before renewal is required.
9. Remember to save your certification as it is your responsibility to maintain your certification records.
10. The IRB Office will be notified when your training is complete.

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. If there is an external IRB Authorization Agreement (IAA) the currency of training will be the responsibility of the CFVHS Principal Investigator.