

GME Scholarly Activities & Human Research Protection Training

Requirements:

All Residents and Trainees conducting scholarly activities and/or research activities such as, design, conduct, or analysis of case reports, quality improvement projects, and human subjects research, or accessing identifiable information covered under HIPAA regulations is required to complete certification training through CITI Training prior to submitting a project to the GME or IRB for determination or approval.

Additional training may be required for individuals when conducting activities at other institutions or other organizations. It is the residents or trainee's and their advisor/mentor's responsibility to know and obtain the required training. The GME Research Program or IRB Office can assist investigators in locating additional training courses.

- 1. <u>All</u> CFVHS residents and trainees must complete the following courses hosted by CITI Programs:
 - a. CITI Health Information Privacy and Security for Investigators (HIPS), and
 - b. Biomedical Responsible Conduct of Research (RCR); and
 - c. Group 1: Residents & Trainees (HSR)
 - d. If expired, completion of the associated refresher course is required. After three cycles of refresher training, the basic course must be completed.
- 2. Non-Resident/Trainee personnel listed on a Case Report or Quality Improvement project are not required to obtain human subject protection training.
- 3. Personnel listed (not necessarily authors) on a https://example.com/html/ Personnel listed (not necessarily authors) on a https://example.com/html/ Project must complete one of the Human Subjects Protections Training course hosted on the CITI Programs based on the type of research activities conducted. Please see IRB Guidance: Human Research Protection Training on the IRB website for detailed information regarding the appropriate training required.
- 4. Non-affiliated researchers and project personnel listed on a human research project must complete a similar human research protections training program Please contact the IRB office for guidance.

Instructions:

- 1. Go to CITI Program home page at <u>CITI Program</u> or <u>Research, Ethics, and Compliance Training | CITI Program</u>.
 - 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 <u>Getting Started</u> 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.

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- 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 only if you are conducting clinical trials research.
 - Question 3: Health Information Privacy & Security select one of the following:
 - Information for Investigators: if you are conducting clinical trials research.
 - o Information for Clinicians: all other users.
 - Question 4: Financial Conflicts of Interest (FCOI) select only if you are conducting clinical trials research or funded research.
 - Question 5: Responsible Conduct of Research all residents and trainees 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 and transcript as it is your responsibility to maintain your certification records.
- 10. The GME Research Program will be notified when your training is complete. You **must** use your CFV email address as your primary email in CITI for this to work.

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