

**The Carle Foundation
Research Institute – Policy 102**

Subject	Education Requirements for Investigators and Key Personnel Involved in Research				
Approval	Mar 2008	Review	Dec 2009	Revision	Dec 2009
Purpose	Investigators and key personnel must be fully aware of and embrace their responsibilities to protect the rights and welfare of research subjects. For this reason, education requirements have been established for those conducting research.				

Education Requirements

1. Initial Education

Beginning January 1, 2009, all new study submissions to the Carle Institutional Review Board (Carle IRB) require the investigators and all key personnel to have completed the initial education requirements. A delay in completing the education requirements will result in a delay of review and approval by the Carle IRB. Initial training should include biomedical Human Subject Protection, HIPAA in research, and Conflicts of Interest in research. This requirement can be met through registering as a Carle Foundation Hospital (CFH) affiliate with CITI at www.citiprogram.org and completing the required modules and/or in combination with obtaining credits for NIH/UIUC education described below under items 4-7.

2. Continuing Education

Once initial training requirements are met, investigators and key personnel must also complete:

- a. at least one (1) hour of seminar attendance or on-line training each year on investigator obligations under the Carle IRB's policies and procedures; **and**
- b. continuing education in human subject protection every 2 years by taking the refresher course of the CITI training as a CFH affiliate.

For studies approved by the Carle IRB prior to January 1, 2009, initial training requirements must be met before the next IRB submission (continuing review) but no later than January 1, 2010.

If the training requirements are not met on the date of study expiration, the study will be put on Administrative Hold for up to 14 calendar days. If the training requirements are not met during this 14 day hold period, the study will be closed by the Carle IRB. To reopen the study, the investigator(s) must submit the study for initial review and meet the education requirements.

Options for Completing the Requirements

1. Initial Education

- a. **CITI Education:** Training is available at www.citiprogram.org by logging in as a CFH affiliate. This web-based course will take 3 to 6 hours to complete depending on an individual's prior knowledge and experience with research, ethical principles and regulations about human subject protections and CITI course requirements.
- b. **Instructions:**
 - Complete the required modules, which include: HIPAA and Conflict of Interest in Research and the required elective module/s. (The elective module/s are your choice within the list of modules provided by CITI under the elective category.) Complete the required quizzes.
 - Achieve an overall passing score of 80% or higher on each quiz.
 - Complete the Course Completion Form at the end of the course.
 - Additional elective modules are also available for those seeking more information.

2. Credit for University of Illinois at Urbana-Champaign (UIUC) education

- a. **Option 1**, consisting of the completion of:
 - UIUC Human Subjects module and quiz
 - NIH human subject protection training
 - 'HIPAA and Human Subjects Research' CITI module
- b. **Option 2**, consisting of the completion of:
 - UIUC Human Subjects module and quiz
 - CITI modules that are required by UIUC
 - 'HIPAA and Human Subjects Research' CITI module.

Options for Completing the Requirements (cont.)

3. Credit for NIH Education

- a. NIH human subject protection training completed after March 1, 2008, can be applied toward the completion of the education requirement. The NIH certificate of completion must be forwarded to the Carle CITI Administrator at the HSP Office. In addition, researchers must register with CITI as a CFH affiliate and complete the following five (5) CITI modules:
 - Social and behavioral research for biomedical researchers
 - FDA regulated research
 - HIPAA and human subjects research
 - Conflicts of interest in research involving human subjects
 - One CITI elective

4. **Exempt Research Education:** Those investigators and key personnel who will only be conducting exempt research may opt to complete the shorter Exempt Research Education through CITI after logging in as a CFH affiliate. This education will need to be updated to the full CITI training should the investigator begin conducting research that is classified as expedited or full board.

5. Continuing Education

a. Annual Education

You can obtain at least one (1) hour of seminar attendance or on-line training **each year** on Carle IRB's policies and procedures and investigator obligations.

b. Every 2 Year Education

You can obtain continuing education credit **every 2 years** by completing the **CITI Refresher Course** – This web-based course covers research, ethical principles and regulations about human subject protections. These are required and elective modules.

- c. **Exempt Research Education:** Investigators and key personnel involved in only exempt research do not have any continuing education requirements.

Definition of Key Personnel Involved in Research

1. Key personnel include all individuals responsible for the design or conduct of the study. This may include:
 - a. Personnel from subcontractor institutions
 - b. Consultants
 - c. Fellowship applicants and training grant trainees
 - d. Individuals who need not necessarily be paid on the NIH award to be considered 'key personnel' if they are involved in the design and conduct of the study.
2. Individuals who have minor roles in the research are not required to be listed on the IRB application and are not required to complete the training requirements. However, the Principal Investigator is responsible for ensuring that these individuals receive adequate training in accordance with their roles in the research.

Certificates and Training History

1. All CITI certificates for CFH affiliates get automatically sent to the Carle IRB. All other individual training records must be submitted to the Carle HSP office (irb@carle.com) no later than the date of a study submission.

CITI training Instructions for Initial or Continuing Education

1. To Register
 - a. Go to www.citiprogram.org and select "New Users Register Here".
 - b. Select your institution: Carle Foundation Hospital.
 - c. CITI requires that you establish a unique username and password for future log-in.
 - d. Enter your required demographic information, denoted by the asterisk.
 - e. After you submit your demographic information you will be asked to select the training you want to take. First choose your appropriate research activity (investigator, IRB member, etc.) and then select if you have or have not completed your basic initial training.
 - f. If you need a step-by-step "Job aid", please email your request to: research@carle.com.

CITI training Instructions for Initial or Continuing Education (cont.)

2. To Complete the Course

- a. Once you have completed your registration, you can immediately begin any modules within the selected education course. As a registered user, you can return to the CITI Course site at any time to complete your training.

3. To Receive Credit

- a. You must complete the required quizzes.
- b. A passing score of 80% or higher must be achieved. (Quizzes can be retaken to achieve a passing score.)
- c. Complete the Course Completion Form at the end of the course when given the option. Print your Certificate of Completion for your records. A notification email will be automatically sent to the Carle CITI administrator upon your completion of the training.
- d. If you miss the opportunity to print the Certificate of Completion and would like one for your files, contact the CITI administrator at research@carle.com.

Electronic Approval On File

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