Investigator and Key Research Personnel Education Requirements and CITI Training Instructions

Training Requirements

IRB Submissions: Beginning January 1, 2009, all study submissions to the IRB will require the investigator and all key research personnel to have completed the initial training requirements.

Initial education parameters for Investigators and Key Research Personnel

CITI training: 12 biomedical modules and 1 Carle IRB local policies module
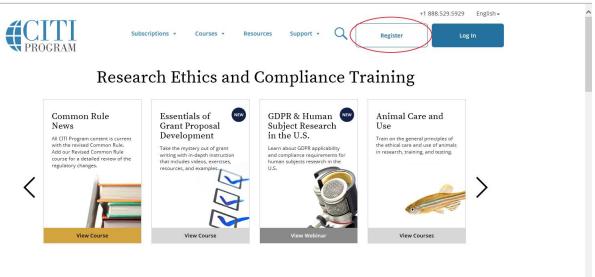
Training Requirement Instructions

CITI training is a web-based training available without charge 24/7 to Carle employees and affiliates. Detailed instructions for accessing the program and completing the training are provided in this document.

The Basic Course will require 4-6 hours to complete. Multiple sessions are encouraged. Once you completed the initial registration, you may log off and log back in at any time—your completed modules will be saved.

Complete the following steps to register as a
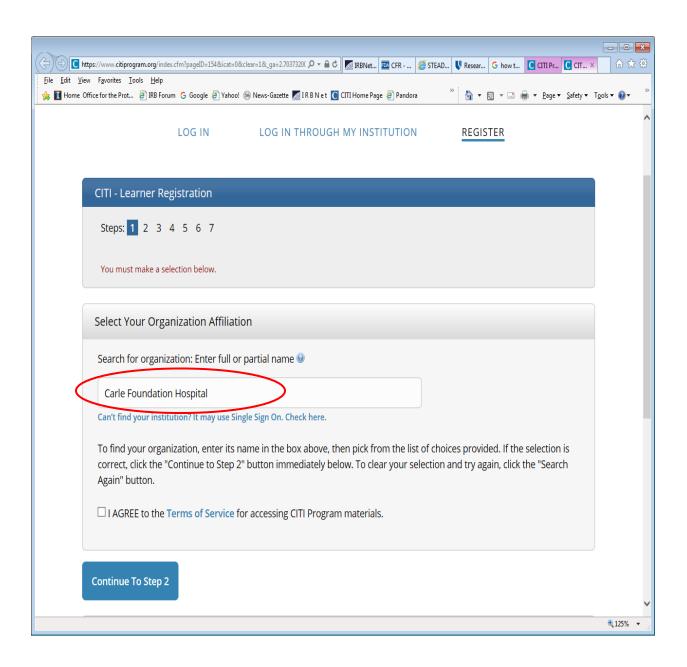
<u>Carle Foundation Hospital Affiliate</u>

1. Log into the CITI course either by typing this IP address in your browser or clicking this link: http://www.citiprogram.org/. Please direct questions to the Human Subject Protection Office at 217-326-4509.
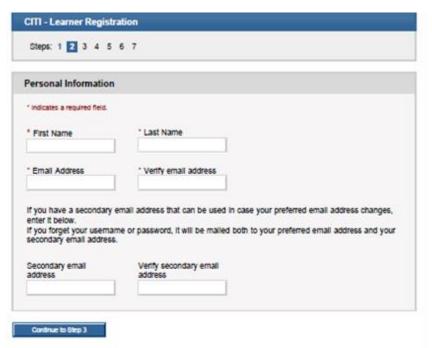2. Click on "Register" in the upper right-hand corner of the screen.

3. To register, complete steps 1-7 below:
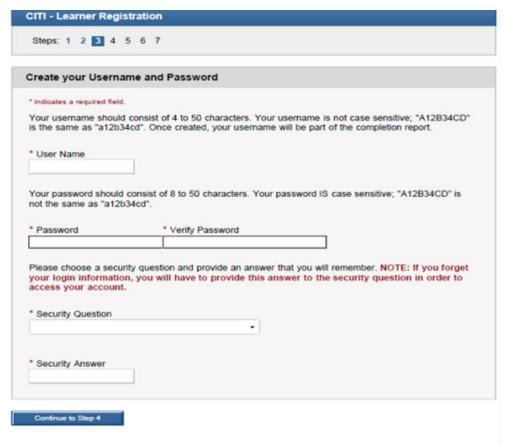
Step 1. Select a participating organization

Select from the drop down box or type in "Carle Foundation Hospital"

Step 2. Enter User information.

CITI - Learner Registration

Steps: 1 **2** 3 4 5 6 7

Personal Information

* indicates a required field.

* First Name   * Last Name

* Email Address   * Verify email address

If you have a secondary email address that can be used in case your preferred email address changes, enter it below.
If you forget your username or password, it will be mailed both to your preferred email address and your secondary email address.

Secondary email address   Verify secondary email address

Continue to Step 3

Step 3. Create Your User Name and Password

CITI - Learner Registration

Steps: 1 2 **3** 4 5 6 7

Create your Username and Password

* indicates a required field.

Your username should consist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as "a12b34cd". Once created, your username will be part of the completion report.

* User Name

Your password should consist of 8 to 50 characters. Your password IS case sensitive; "A12B34CD" is not the same as "a12b34cd".

* Password   * Verify Password

Please choose a security question and provide an answer that you will remember. **NOTE: If you forget your login information, you will have to provide this answer to the security question in order to access your account.**

* Security Question

* Security Answer

Continue to Step 4

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Step 4. Enter Personal Information

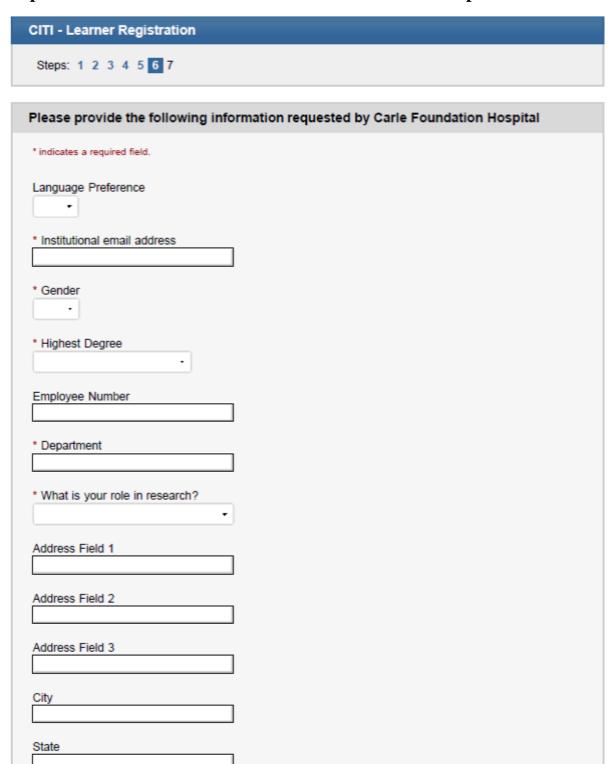**CITI - Learner Registration**

Steps: 1 2 3 **4** 5 6 7

Gender, Ethnicity and Race

Why does CITI Program ask about your gender, race and ethnicity?
Why does CITI Program use these categories?
Why does CITI Program ask about your gender?

* indicates a required field.

* Your Gender Is:

○ Male

○ Female

○ I would rather not disclose

* Your Ethnicity Is: (You may choose only one)

○ Hispanic or Latino

○ Not Hispanic or Latino

○ I would rather not disclose

* Your Race Is: (You may choose more than one)

☐ American Indian or Alaska Native

☐ Black or African American

☐ Asian

☐ Native Hawaiian or Other Pacific Islander

☐ White

☐ I would rather not disclose

Continue to Step 5

Step 5. Additional Questions

CITI - Learner Registration

Steps: 1 2 3 4 **5** 6 7

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?

If you answer "yes", you will be provided with information **before** you start a CEU-eligible course about the amount of credit available, information about the course authors, and other required CEU disclosures. This information **must** be viewed before a course is started in order for you to be eligible to purchase CEU credit after course completion. However, answering "yes" does not obligate you to purchase CEU credits for any course.

If you answer "no", you will **not** see information about the CEU credits available for courses before you start them or after completing them, and you will be **ineligible** for CEU credit for these courses. You can change this preference at any time by clicking on a "CEU Information" link or using a "My Profile" link to update your Profile.

If you're not sure, you can change your answer later.

○ Yes
○ No
○ Not sure. Ask me later

If you answered "yes", please check all the types of CEU credit that may be of interest. This information allows us to ensure that you receive appropriate Pre- and Post-Course information relevant to the kind(s) of CEU credit that you may request.

☐ AMA PRA Category 1 Credits
☐ Nurses (CNE Credits)
☐ Other
☐ Psychologists (CEP Credits)

* Can CITI Program contact you at a later date regarding participation in research surveys? ☺

○ Yes
○ No
○ Not sure. Ask me later

Continue to Step 6

Step 6. Additional Information for Carle Foundation Hospital

CITI - Learner Registration

Steps: 1 2 3 4 5 **6** 7

Please provide the following information requested by Carle Foundation Hospital

* indicates a required field.

Language Preference

[▾]

* Institutional email address

[ ]

* Gender

[▾]

* Highest Degree

[▾]

Employee Number

[ ]

* Department

[ ]

* What is your role in research?

[▾]

Address Field 1

[ ]

Address Field 2
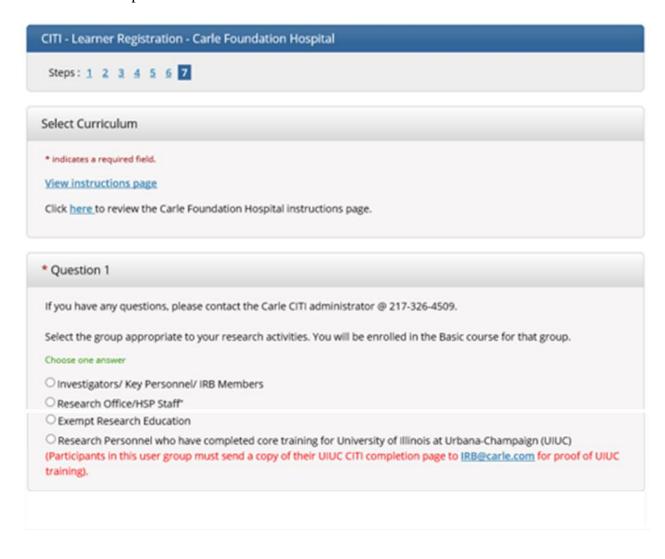
[ ]

Address Field 3

[ ]

City

[ ]

State

[ ]

Zip/Postal Code

Step 7. Choosing the appropriate group for your research activity at Carle

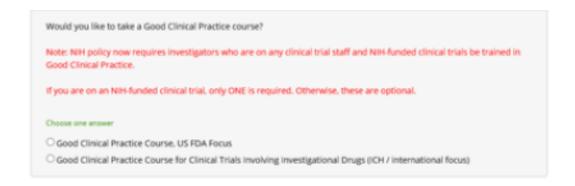**Question 1:** select the bubble that describes your position in the research study.

- If you have any questions as to which course you need, please call 217-326-4509
- Be advised that we have one combo group, **Research Personnel who have completed core training for University of Illinois at Urbana-Champaign (UIUC).** If you select this group, you must email certificates from **UIUC** to the **IRB** office for proof of completion.

CITI - Learner Registration - Carle Foundation Hospital

Steps : 1 2 3 4 5 6 **7**

Select Curriculum

* indicates a required field.

View instructions page

Click here to review the Carle Foundation Hospital instructions page.

* Question 1

If you have any questions, please contact the Carle CITI administrator @ 217-326-4509.

Select the group appropriate to your research activities. You will be enrolled in the Basic course for that group.

Choose one answer

○ Investigators/ Key Personnel/ IRB Members

○ Research Office/HSP Staff˙

○ Exempt Research Education

○ Research Personnel who have completed core training for University of Illinois at Urbana-Champaign (UIUC)
(Participants in this user group must send a copy of their UIUC CITI completion page to IRB@carle.com for proof of UIUC training).
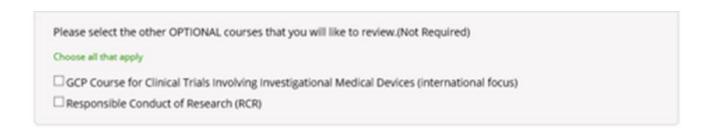
Question 2: Currently, Conflict of Interest training is only required for those researchers who plan to apply for federal funds from the Public Health Service (PHS) to support their research; or for those researchers who are currently engaged in research on PHS funded projects. Sources of PHS funding for research include the National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC) and Agency for Healthcare Research and Quality (AHRQ). Go to http://www.hhs.gov/about/orgchart/ for a complete listing of all PHS agencies. If this does not apply to you, check "no."

Would you like to take the Conflicts of interest course?

Currently, Conflict of interest training is only required for those researchers who plan to apply for federal funds from the Public Health Service (PHS) to support their research; or for those researchers who are currently engaged in research on PHS funded projects. Sources of PHS funding for research include the National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC) and Agency for Healthcare Research and Quality (AHRQ). Go to http://www.hhs.gov/about/orgchart/ for a complete listing of all PHS agencies. If this does not apply to you, check "no."

Choose one answer

○ Yes
○ No

Question 3: Would you like to take a Good Clinical Practice course? NIH policy now requires investigators who are on any clinical trial staff and NIH-funded clinical trials be trained in Good Clinical Practice, and only ONE is required. If this does not apply to you, do not check either.
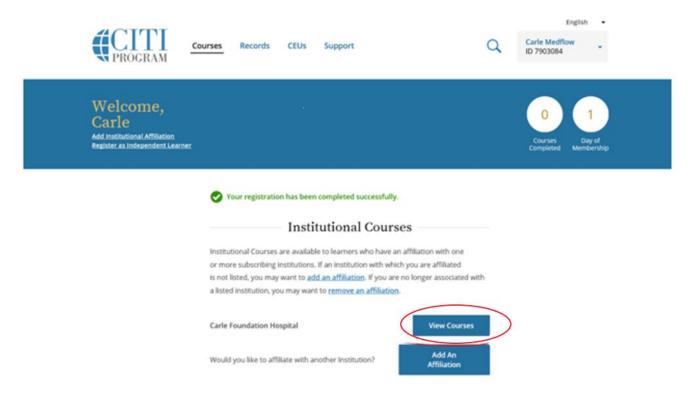
Would you like to take a Good Clinical Practice course?

Note: NIH policy now requires investigators who are on any clinical trial staff and NIH-funded clinical trials be trained in Good Clinical Practice.

If you are on an NIH-funded clinical trial, only ONE is required. Otherwise, these are optional.

Choose one answer

○ Good Clinical Practice Course, US FDA Focus
○ Good Clinical Practice Course for Clinical Trials Involving Investigational Drugs (ICH / International focus)

Question 4: Please select the other OPTIONAL courses that you will like to review. If you do not want to take these courses, do not check either.

Please select the other OPTIONAL courses that you will like to review.(Not Required)

Choose all that apply

☐ GCP Course for Clinical Trials Involving Investigational Medical Devices (international focus)

☐ Responsible Conduct of Research (RCR)

Click "Complete Registration"

This will take you to the CITI PROGRAM home page. Click "View Courses" and begin your CITI training.

The **Basic Course** will require 4-6 hours to complete. Multiple sessions are encouraged.

To Complete the Course:

- The minimum "passing" aggregate score for each quiz is 80%. A running tally is compiled in the Grade Book.   You may repeat any quiz on which you scored less than 100%, should you desire to improve any of your quiz scores.

- Print or download a **Course Completion Report** as evidence that you have met your institutional requirements. A copy will be sent **automatically** to your institutional administrator.   You may also return to the course site in the future to obtain a copy of the completion report.

- Submit a voluntary, anonymous user satisfaction survey.