

## Purpose

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Trinity Health Of New England's Institutional Review Board (IRB) requires all investigators, study coordinators, and research staff to complete training in the protection of human subjects before receiving protocol approval. This training ensures investigators are qualified, upholds Belmont Report principles, and complies with IRB regulations.

Currently, the IRB provides and accepts CITI training. Off-site investigators collaborating with an approved site must affiliate their CITI training account with Trinity Health of New England and complete the required courses.

Individuals who do not meet training requirements cannot participate in human research. The IRB may withhold or revoke protocol approval if training is not completed. New investigators or staff added to a protocol after approval must also fulfill training requirements before engaging in human research.

## Steps and Procedures:

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1. Navigate to the CITI website: <https://www.citiprogram.org/>

## To establish a new CITI account -

2. Click the **Register** button on the main page of the CITI website and enter the appropriate information as indicated for the following:
  - Organization Affiliation: **Trinity Health – Michigan Region**
    - Agree to the Terms of Service and Privacy Policy
    - Affirm that you are an affiliate of Trinity Health – Michigan Region
  - Personal Information: Enter name & email address
  - Create Username & Password
  - Demographic Information
  - Option for receiving Continuing Education Unit (CEU) (*charges may apply*)

## If you already have a CITI account -

3. Log in to CITI and confirm you are affiliated with **Trinity Health – Michigan Region**
  - Select **Add a Course** from the menu

Select Add a Course

Learner Tools for Trinity Health - Michigan Region

- [Add a Course](#)
- [Remove a Course](#)
- [View Previously Completed Coursework](#)
- [Update Institution Profile](#)
- [View Instructions Page](#)
- [Remove Affiliation](#)

**Investigators, Study Coordinators and other members of the study team with need to add the following courses:**

- 1) Human Subjects Research (HSR)
- 2) Good Clinical Practice (GCP)
- 3) Responsible Conduct of Research (RCR)
- 4) Conflict of Interest (COI)
- 5) Biosafety/Biosecurity (BSS) **optional**
- 6) Clinical Research Coordinator (CRC) **optional**

### Question 1

#### Human Subjects Research (HSR)

Would you like to enroll into the Human Subjects Research course?

- Yes  
 Not at this time.

### Question 2

#### Good Clinical Practice (GCP)

Would you like to enroll into the Good Clinical Practice course?

- Yes, enroll me in the Basic course.  
 Yes, enroll me in the Refresher course (Select this option if your sponsor requires you to take the updated E6(R3) revision of the ICH Guideline for Good Clinical Practice.)  
 Not at this time.

### Question 3

#### Responsible Conduct of Research (RCR)

Would you like to enroll into the Responsible Conduct of Research course?

- Yes  
 Not at this time.

### Question 4

#### Conflicts of Interest (COI)

Would you like to enroll into the Conflicts of Interest course?

- Yes  
 Not at this time.

Investigators & study team will answer **YES** to questions 1, 2, 3, & 4

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### Question 5

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#### Biosafety/Biosecurity (BSS)

Would you like to enroll in the Biosafety/Biosecurity course? **ONLY those who are responsible for shipping research biological materials are required to take this course.**

- Yes
- Not at this time.

\*Questions 5 & 6 are optional

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### Question 6

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#### Clinical Research Coordinator (CRC)

Would you like to enroll in the Clinical Research Coordinator course? **ONLY those who are assigned clinical research coordinator tasks and responsibilities are required to take this course.**

- Yes
- Not at this time.

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### Question 7

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#### Institutional/Signatory Official (IO)

Would you like to enroll into the Institutional/Signatory Official course? **ONLY the Institutional/Signatory Official is required to take this course.**

- Yes
- Not at this time.

Select **NOT AT THIS TIME** to Questions 7 & 8

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### Question 8

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#### IRB Chair (IRB)

Would you like to enroll into the IRB Chair course? **ONLY IRB CHAIR, CO CHAIR, and VICE CHAIR are required to take this course.**

- Yes
- Not at this time.

Submit

**Forgot your CITI Username and Password?** To retrieve your Username or Password click **Forgot** from the CITI login page. *To retrieve your CITI Username:* enter your email address. *To retrieve your CITI Password:* enter your email address and Username.