

# Corewell Health Research Institute CITI Human Subjects Research Training Program

Corewell Health requires all individuals involved in the conduct of human subjects research to obtain training in human subjects protection by completing the *Biomedical Human Subjects Research Course* provided through CITI. Any research team member identified on the IRB application must complete this training.

## Registration

1. Go to the Collaborative Institutional Training Initiative (CITI) website <http://www.citiprogram.org>
2. Log into your CITI account or Register:
  - a. **FIRST TIME USERS:** Register where indicated. You will then create a user ID and password for ongoing access to the training courses
  - b. Registered Users may use the “Forgot?” features to retrieve a username or password. **DO NOT CREATE MULTIPLE CITI ACCOUNTS.** Multiple accounts create delays in processing IRB submissions.
3. Within the "Select Your Institution or Organization" screen, go to the first dropdown box "Participating Institutions," and affiliate your account with Corewell Health. **Failure to affiliate with Corewell Health will prevent the IRB from verifying your training completion.**
4. Complete the demographic profile as presented on the next screen.

## Class Selection

5. You will be asked a series of questions. Based upon your responses, you will be assigned courses to complete. Learners must complete the **Biomedical Human Subjects Research Course** to satisfy IRB mandatory requirements.
6. Investigators and team members who are key personnel on NIH or industry-funded **clinical trials** must additionally take the **Good Clinical Practices (GCP) for Clinical Trials Course**.
  - a. Note: Clinical research operations team members are required to complete this course during onboarding and maintain this certification throughout their employment.
7. Some questions will allow you to select **Optional** or **Laboratory Animal** training courses. Select these courses if they apply. It is not required to

complete these optional courses to satisfy the IRB human subject research protections training requirement.

8. Click **Start Now** under the list of **Courses Ready to Begin**.

## CITI Refresher Course

Corewell Health requires renewal of your **Biomedical Human Subjects Research Course** every three (3) years. If you already completed initial training, you will be able to access the **“Refresher Course”** ninety days prior to your certification expiration.

- Log in to your CITI account
- Click on the **My Records** tab. You will see the course listed as due for renewal.
- Select the **Biomed Refresher Course** by clicking on **View**, under **Gradebook**. Complete the course.

## Scoring and Completion Certificates

1. Course Completion:
  - a. **Biomedical Human Subjects Research Course:** Complete all **8 required modules** and obtain a **cumulative score of 80%** or greater. In the event this score is not achieved, the learner will be asked to repeat the module.
  - b. **Good Clinical Practices (GCP) for Clinical Trials Course:** Complete all **13 required modules** and obtain a **cumulative score of 80%** or greater. In the event this score is not achieved, the learner will be asked to repeat the module.
2. It is the responsibility of the Principal Investigator to ensure the required training is completed and maintained for all study personnel.
  - a. If you need to determine if a research team member has completed their assigned course curriculum, ask them to log into to their CITI account and provide you with their certificate.
  - b. The IRB does not retain study completion certificates.

## FREQUENTLY ASKED QUESTIONS

1. How long will it take to complete training?

The average learner requires 3-4 hours to complete the **Biomedical Human Subjects Research Course**. Training must be “refreshed” **every 3 years**. The average learner requires approximately 2 hours to complete the **Refresher Course**. You do not have to complete the modules all at one time.

## 2. Is training a “one time only” requirement?

**No.** The **Biomedical Human Subjects Research Course** certification is valid for **3 years**.

Similarly, the Good Clinical Practices (GCP) for Clinical Trials Course certification is valid for **3 years**.

Ninety (90) days prior to expiration, CITI will send you a reminder via e-mail to take a Refresher Course. Please verify the e-mail address you registered with is still valid to ensure that you receive the reminder notice and avoid training expiration. If you continue to participate in research, you must complete a Refresher program every 3 years.

## 3. What if my training expires and I still want to work on a study?

If your training expires and you are listed as an investigator or key personnel on an active study, you will be removed from the project and must stop participating in research until the training is completed.

## 4. Will I be responsible for any charges?

**No.** There is no charge to the individual or their department for CITI training. You will complete training under the Corewell Health Research system subscription.

## 5. I have two accounts (ex. due to name change, using multiple email addresses). Can I merge them into one CITI Program account?

If you would like to merge two learner accounts, please send an e-mail to [support@citiprogram.org](mailto:support@citiprogram.org) and include the following information:

- Your first and last name.
- The name of your institution.
- The username or Member ID for the account to keep.
- The username or Member ID for the account to merge.
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For further assistance please contact the CITI Program help desk at 888.529.5929 or e-mail: [support@citiprogram.org](mailto:support@citiprogram.org).

#### 6. I need to check which courses I have completed in the past. How do I do this?

Click on the **My Records** tab. Course which are in progress (listed as ACTIVE) and courses you have completed are listed. You can choose to view-print-share your **Completion Records**.

#### 7. I took the CITI program at another institution. Can I transfer my completion records to Corewell Health, or do I need to repeat the CITI program?

**Yes.**

You can transfer your training records from the other institution to Corewell Health. You must log into your CITI account and update your profile, affiliating your account with both institutions (your previous institution and Corewell Health).

- Log into your existing CITI account. On the first page, add Corewell Health as an affiliation.

Once you are enrolled in the course, any modules that are shared between the institutions will have their credit transferred automatically.

Corewell Health may require you to complete more or different modules than your previous institution.

After you affiliate with Corewell Health, click on the **My Records** tab. In the drop down for "Show Records for" ensure you have selected **Corewell Health**. Under **Biomedical Human Subjects Research Course**, ensure the **Completion Date** is populated. If no completion date is displayed, you must complete additional courses to meet Corewell Health requirements, click on the **My Course** tab. Under **Active Courses**, select the course and complete outstanding modules.

## Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to [add an affiliation](#). If you are no longer associated with a listed institution, you may want to [remove an affiliation](#).

### 8. Are additional modules and courses, beyond the required modules and courses, available to me?

In addition to required training, you can complete Supplemental Modules within the required courses. In the **Biomedical Human Subjects Research Course**, under “**Required Modules**,” 8 required modules listed. Under **Supplemental Modules**, 12 optional modules are listed.

To complete Supplemental (or optional) modules, simply click on **Start** beside the module name. For a list of required and supplemental modules, refer to Appendix I.

#### Additional Courses Available to Corewell Health Learners

During the CITI program account registration process, you can select additional courses by answering enrollment questions. Simply follow the prompts to add any additional courses that align with your needs. If you have already completed registration and would like to add additional courses, follow these steps;

- On the Main Menu, locate the selection for your Corewell Health’s courses.
- Click “Add a Course”
- Answer the enrollment questions to select additional courses and submit.

For a list of **Biomedical Human Subjects Research Course modules and additional courses**, refer to Appendix I.

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## Contact Information

For more information contact Jessica Verbos at  
[Jessica.Verbos@corewellhealth.org](mailto:Jessica.Verbos@corewellhealth.org)

### Appendix I: CITI Supplemental Modules and Additional Courses

## Biomedical Human Subjects Research Course

This course consists of 8 required modules and 12 supplemental (optional) modules.

Required Modules
Populations in Research Requiring Additional Considerations and/or Protections
Conflicts of Interest in Human Subjects Research
History and Ethics of Human Subjects Research
Basic Institutional Review (IRB) Regulations and Review Process
Informed Consent
Records-Based Research
FDA-Regulated Research
Research and HIPAA Privacy Protections
Supplemental (Optional) Modules
Students in Research
Avoiding Group Harms-US Research Perspective
Phase I Research: Understanding Phase I Research
Phase I Research: Protecting Phase I Subjects
Data and Safety Monitoring in Human Subjects Research
Belmont Report and its Principles
Genetic Research in Human Populations
Research Involving Children
Research Involving Pregnant Women, Fetuses, and Neonates
Social and Behavioral Research (SBR) for Biomedical Researchers
International Studies
Vulnerable Subjects-Research Involving Workers/Employees

## Additional Courses Available to Corewell Health Learners

The following additional CITI courses are available:

Course in International Studies
Responsible Conduct of Research (RCR) Course in Biomedical Sciences
Health Information Privacy & Security (HIPS) Course
Course Series for Research Involving Laboratory Animals
Revised Common Rule