



## Sub-I Training Requirements

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### GCP Training

Good Clinical Practice (GCP) Training is a requirement for all staff participating in a clinical trial. This training will take approximately one hour (if using the reference material provided in this zip drive in an open book forum). *This certification will then last for 2 years.*

1. Please login to <https://gcp.nidatraining.org/>

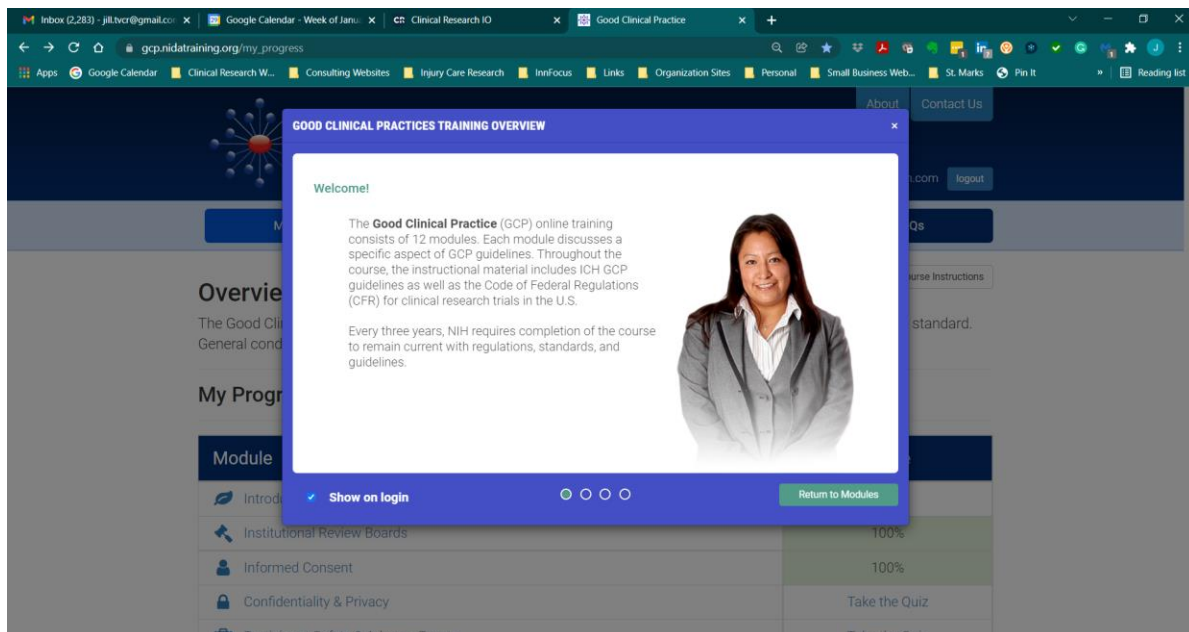
A screenshot of the GCP Training website. At the top, there is a navigation bar with three buttons: "Welcome", "Resources", and "FAQs". Below this is a green banner that says "You are now logged out." Underneath is a blue box titled "Updated GCP Course" containing text about the website being up-versioned and a link to the new site. The main content area is titled "Welcome" and contains a paragraph about the GCP course, a link to preview enhanced features, and instructions on how to begin. To the right of the text is a "Login" form with fields for "email" and "password", a "Forgot password?" link, a "Sign in" button, and a "Need an account? Sign up here!" link. At the bottom left of the page, there is a small image of a diverse group of people.

2. Click on Sign up Here

The screenshot shows a 'Create an Account' form with the following fields and options:

- Welcome** | **Resources** | **FAQs**
- Create an Account**
- Please enter your first and last name as you would like it to appear on your certificate. You will **NOT** be able to change your name later.
- First Name\*** [Text Input]
- Last Name\*** [Text Input]
- Study Role/Title\*** [Text Input]
- Organization\*** [Text Input]
- Location\*** [Dropdown Menu: United States]
- If Other Please Specify** [Text Input]
- NIH-Affiliated\***
  - Yes ☐ No ☐
- My IRB requires a 100% passing grade.\***
  - Yes ☐ No ☐

3. Enter your Name: I think you have this one covered. 😊
- Study Role/Title: (Please enter PRINCIPAL INVESTIGATOR in this field)
- Organization: (Please enter CARE INSTITUTE in this field)
- NIH Affiliated: No
- IRB requires 100% Passing Grade: No
- Then complete your email and password and click submit.
- You should see the below screen.



4. Click on Return to Modules

The screenshot shows the 'Good Clinical Practice' website. The top navigation bar includes a logo, the site name, a user email 'jill@injurycaresearch.com', and a 'logout' button. Below this is a secondary navigation bar with buttons for 'Modules', 'Resources', 'Certification', and 'FAQs'. The main content area is titled 'Institutional Review Boards' and features a red 'Take the Quiz' button. A progress bar shows modules 1 through 9, with module 1 highlighted. A list of topics for the IRB module is provided, including 'Part 1: What is an Institutional Review Board (IRB)?' through 'Part 9: Summary of Key Points'. A 'Return to Previous Module' link is at the bottom.

5. In the top right corner of each module you can go directly to “Take Quiz.” Then use the PDF files in the zip drive provided to complete the quiz via open book forum. A passing score of 80 will be necessary to complete the module.

The screenshot shows the 'Certification' page. It has a navigation bar with 'Modules', 'Resources', 'Certification', and 'FAQs'. The main heading is 'Certification', followed by a 'Print Certificate' button. The section 'Your Current Certificate' contains a list of instructions: 1) Once all required quizzes are completed with a score of 80% (or 100%), the certificate will appear. 2) To print, click the 'Print Certificate' button; the certificate will be downloaded as a PDF. 3) The current certificate is available for download until you recertify. 4) A tip to download the certificate for historical record. The 'Recertify (Please read carefully before taking action)' section includes instructions: 1) If completed, read and follow the instructions. 2) Current quiz scores cannot be applied towards recertification; all required knowledge must be demonstrated by retaking quizzes.

6. Once all modules are complete please click on “Certification” at the top tool bar and print your certificate. It will create a PDF of your certificate.
7. Please email this to [Jill@CardioRenalInstitute.com](mailto:Jill@CardioRenalInstitute.com) and [Mustafa@CardioRenalInstitute.com](mailto:Mustafa@CardioRenalInstitute.com)

## Clinical Research IO (CRIO) Login

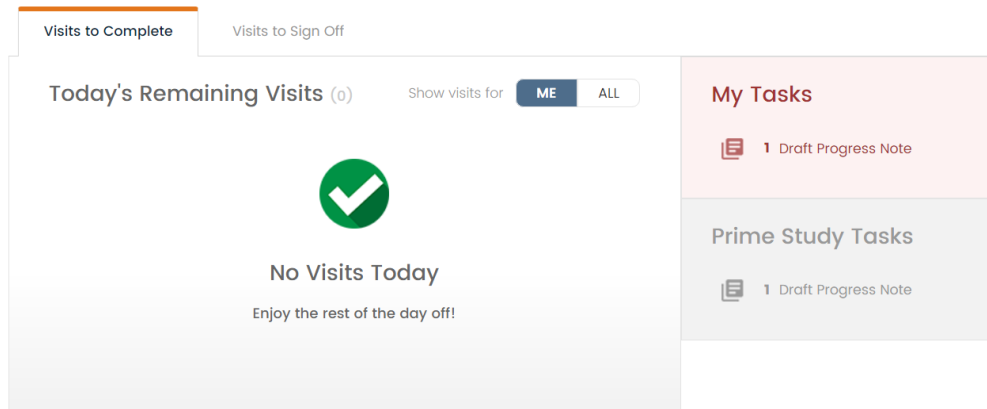
This is our software that we will be using to track patient visits. The below training will teach you how to use the system. That said, you'll always have a CRC available to help you with navigating this environment as well.

1. You'll receive an invite into CRIO via email. Login and reset your password. Login Link: <https://app.clinicalresearch.io/login>

## CRIO Training

1. Click on the help button in the bottom right corner.

### My Dashboard



2. Click on "Academy." This will redirect you to a new environment.

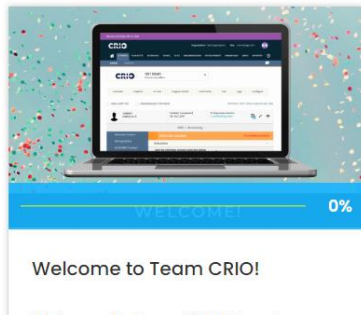
## Academy



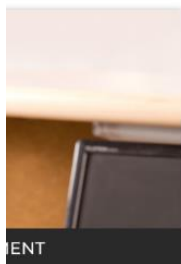
### ENROLLED COURSES

### ADD AVAILABLE COURSES

### COMPLETED COURSES



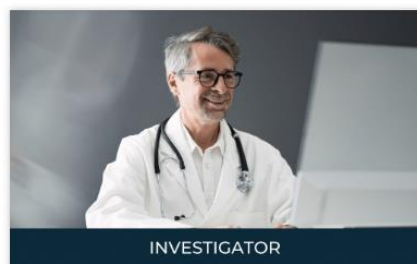
- Click on "Add Available Courses" and then please enroll in "Investigator Training" (25 minutes) and "Investigator Certificate" (8 minute test over the material).



Investigator Training

Study Lists and  
Recruitment

1956 Enrolled



CRIO Investigator Training

Learn how to use and manage  
eSource and eRegulatory for study as  
a principal investigator. Topics...

25 minutes

1324 Enrolled



CRIO Investigator Training  
Certification

For Investigators, test your knowledge  
after completing CRIO Investigator  
Training...

8 minutes

942 Enrolled

- Once completed with the certificate please send to: [Jill@CardioRenalInstitute.com](mailto:Jill@CardioRenalInstitute.com)

## Protocol Specific Documents and Training

The above trainings are not study specific. They are general and must be completed before we can add you to any research activity. Then, for each protocol you will be assisting the PI with, there are a few items that we'll need.

1. **Financial Disclosure Form**: This will be sent to you for eSignature via Adobe Sign. Financial Disclosure Forms (FDFs) are required by the FDA prior to starting a study as well as one year after the study is completed. On these forms if you or any immediate family member has any financial interest in the study Sponsor or the Investigational Product (IP) being studied these must be disclosed using this form.
2. **Documentation of Protocol Training**: Prior to working on any protocol there MUST be documentation in place that you have reviewed the protocol and been trained on both the IP administration, mechanism of action, protocol specific procedures and the protocol in general. This is documented either via attending the Site Initiation Visit (SIV), Investigator's Meeting (IM), or on a training document. The Regulatory Department or your Clinical Research Coordinator (CRC) will assist you with ensuring this is completed prior to your involvement in the study.
3. **Delegation Log Sign-off**: Before any research personnel are allowed to work on a study the Principal Investigator must delegate this task to each staff member. At CARE this is completed through CRIO. You will receive an email from the Regulatory Department or your CRC that this Delegation Log is ready for you to sign of. This email will include specific instructions on HOW that is to be completed.

## Questions/Contact Information

If you have any questions on any of these above steps please contact:

Jill Heinz  
Chief Executive Officer  
CARE Institute  
[Jill@CardioRenalInstitute.com](mailto:Jill@CardioRenalInstitute.com)  
208-841-8624 (cell)  
208-984-2273 (office)