

## **Getting Started With the MetroHealth Institutional Review Board**

For someone who is entirely new to the MetroHealth IRB system, there are several steps for you to take:

1. eIRB Registration (MetroHealth's electronic IRB system)
2. CREC Registration / Completion of CITI Courses
3. Continuing Certification
4. MetroHealth's Conflict of Interest (COI)

**Please note - COI, eIRB registration, and CREC registration are three separate steps.**

### **MetroHealth eIRB Registration**

MetroHealth's IRB system is completely electronic and requires its users to be registered into the system.

Enter the MetroHealth IRB website. <https://irb.metrohealth.org/eIRB>

#### **MetroHealth Investigators (i.e., those with a MetroHealth email address):**

Click "MHS Employee Login". Your login credentials will be your full MetroHealth email address (including @metrohealth.org) and MetroHealth network password. If you are unable to login, then please contact the IRB Staff for assistance.

#### **Non-MetroHealth Investigators (i.e., those without a MetroHealth email address):**

If you do not have a MetroHealth email address but have login credentials for the Compliance Department's CONI system, click "Non-MHS Employee Login" and enter your CONI Credentials.

If you had an IRB account in the old electronic IRB system but do not have either of the above login credentials, then please contact the IRB staff for a password reset.

If you are unable to login via any of the avenues described above, then please fill out the "IRB User Access Request" form on the IRB homepage - [IRB User Access Requests \(smartsheet.com\)](https://smartsheet.com). An IRB staff member will contact you with the next steps. **Please note that this is NOT an automatic process.** Usually, within two business days, the IRB will send you your login credentials or contact you with next steps. If you do not receive an email following this timeframe, please do not register again. Instead, contact an IRB staff member for assistance.

Note: When applicable, you may be prompted to change the password provided by the IRB to one of your own creation. The system will mention that your password has expired and may prompt you to change it in COI.

## **CWRU’s CREC Registration: Completion of CITI Courses**

The purpose of Case Western Reserve University’s (CWRU’s) Continuing Research Education Credit (CREC) Program is to provide documented training on the protection of human participants in research that is conducted at affiliated institutions. For persons just entering the CREC Program, the first step in the process is to complete the online education program, Collaborative Institutional Training Initiative (CITI) created by the University of Miami.

For assistance with CREC, please email [crec@case.edu](mailto:crec@case.edu).

### **Initial Certification**

*Completion of the CITI Basic Course is the ONLY way to enter Case Western Reserve University’s CREC Program.*

### **To Register with CITI Program**

Go to the CITI online education program to register. [www.citiprogram.org](http://www.citiprogram.org) and Click “Register”

- Step 1: Under “Select Your Organization Affiliation,” type in “Case Western Reserve University”. “Case Western Reserve University CREC Program” will appear. Select this. Click “Continue to Step 2.”
- Step 2: Enter your name, email, and secondary email addresses. Click “Continue to Step 3.”
- Step 3: Create a username—use your MetroHealth email address as your username if you have one. Create a password and security question and click “Continue to Step 4.”
- Step 4: Complete the demographic questions. Click “Continue to Step 5.”
- Step 5: Complete questions on this page. Click “Continue to Step 6.”
- Step 6: Complete all required fields marked with a red asterisk. For “Case Network ID/EMPLID/UHC, MHS, LSVAMC e-mail,” put your MHS email if available. If you have none, use your CWRUID if available, or your institutional email address. For “Affiliated Institution,” choose “MetroHealth.” Click “Continue to Step 7.”
- Step 7: Complete the following steps as applicable:

- **For Question 1**, select either “**Group 1. Biomedical Research Faculty, Staff, and Students**” OR “**Group 2: Social & Behavioral Research Faculty, Staff, and Students.**” Note: It is recommended to select the “Group 1” course if you will be involved in (or if you are not sure if you will be involved in) biomedical research.
- **For Question 3**, if you will be involved in ANY clinical trials with investigational drugs or medical devices, then please select the “**GCP for Clinical Investigations of Drugs and Devices (FDA)**” training course. Otherwise, please select “Not at this time.”
- **For Questions 10, 11, and 12**, if you are required to complete the “**Good Manufacturing Practices (GMP)**,” “**Biotility: Good Documentation Practices (GDP)**,” AND/OR “**Shipping and Transport of Regulated Biological Material**” courses, then you may answer “Yes” to these questions as applicable; otherwise, you may answer “No” since these courses are NOT required for CREC training. Note: These courses are required for the Cancer Care Stem Cell Transplant Program and Immunotherapy Vector Lab.
- **For all other questions that require an answer**, you may select either “Not at this time” or “No” as applicable.
- Click “Complete Registration” and then “Finalize Registration.”

### To Begin Coursework

- Step 1: If you are not already logged into [www.citiprogram.org](http://www.citiprogram.org), do so now. On the Main Menu, click “Case Western Reserve University CREC Program Courses.” You will see a list of courses you are enrolled in with a column titled “Course.” The courses you selected in the step above should be listed here. Click the name of the course to enter the coursework.
- Step 2: Above your list of Required Modules is a blue link titled “Complete The Integrity Assurance Statement.” Click that, read the statement, complete the form, and click “submit.” You will be returned to the list of modules.
- Step 3: Your next module to complete will be highlighted in blue. Click it to enter. Remember, you do not have to complete all the modules at once, but you cannot save your work midway through a test for a module.

There is a total of approximately 20 modules for the “**Group 1. Biomedical Research Faculty, Staff, and Students**” and “**Group 2: Social & Behavioral Research Faculty, Staff, and Students**” courses. Not all of them require tests. The average time required for these courses is about 3-4 hours. Required modules must be completed with a cumulative score of 80-85% or better to pass the course. There is a total of approximately 14 modules for the “**GCP for Clinical Investigations of Drugs and Devices (FDA)**”

course. The GCP course is stated to take about 4 hours and requires a score of 80% for credit.

Once you have successfully completed the training, CITI will notify CWRU directly. Information will be downloaded, and a CREC account will be set up in the database which can be accessed through CWRU's Spiderweb system (<https://research.case.edu/spiderweb/>) if you have a CWRU username and password.

**Your MetroHealth eIRB profile will NOT be automatically updated by CWRU.** The MetroHealth IRB Staff will be responsible for verifying and updating your CREC completion and expiration dates for the eIRB system. Please contact an IRB Staff member to update this information in your profile. Please note that if IRB Staff cannot verify with CWRU that you have completed the CREC training, then they will not update your dates in your profile until the training has been completed.

Please note that the CREC training is good for 3 years.

*What if I completed CITI Program at another institution?* If your CREC training was completed at another institution using CITI Program, there may be modules that CWRU requires that your previous institution did not.

Please refer to the following link for instructions regarding merging courses from your previous institution: <https://case.edu/research/sites/case.edu.research/files/2021-07/AffiliatingCWRUCRECEProgram.pdf>. Please email [crec@case.edu](mailto:crec@case.edu) any questions you have about merging courses as well as if there are any required CWRU courses that you need to complete.

## Continuing Certification

Every three years, you must earn at least 12 credits to maintain your CREC certification. The CREC system ([crec@case.edu](mailto:crec@case.edu)) will send an automated email reminder directly to you 30 days before your CREC certificate expires. **You will not be sent reminders from the MetroHealth eIRB system to do this.** Expired CREC can prevent studies, modifications, and continuing reviews from being able to be submitted if you are on that study. It can also result in delays of IRB approvals. Plan ahead to avoid difficulties for yourself and others on your studies.

There are a number of other opportunities for earning CREC credits. Please visit <https://case.edu/research/faculty-staff/education-and-training/continuing-research-education-credit-crec> for more information on how to earn credits.

**Your MetroHealth eIRB profile will NOT be automatically updated by CWRU.** Please contact the IRB staff to update your CREC dates for your eIRB profile. Please note that if IRB Staff cannot verify with CWRU that you have completed the CREC training, then they will not update your dates in your profile until the training has been completed.

For more information regarding CREC, including accessing your completion reports, please visit the following websites:

<https://case.edu/research/faculty-staff/education-and-training/continuing-research-education-credit-crec#CRECandCITI>

<https://case.edu/research/sites/case.edu.research/files/2023-02/CREC-Important-to-Remember.pdf>

## **The MetroHealth Conflict of Interest Form**

The MetroHealth System uses an online software system called CONI to collect COI disclosures. CONI is now integrated with the IRB system. We request researchers submit COI disclosures at hire, annually, and throughout the year when modifications occur. Expired or incomplete COI disclosures can prevent studies, modifications, and continuing reviews from being submitted and can also result in delays of IRB approvals.

If you are a new MetroHealth employee, you will receive an email from [compliance@metrohealth.org](mailto:compliance@metrohealth.org) with a link inviting you to submit your annual COI disclosure on or around the 15th of the month. Please note that both MetroHealth investigators as well as investigators joining MetroHealth for research from another institution will have a Research Initiated Certification (RIC) generated when added to a study. Your RIC is an acceptable alternative to an annual COI when outside of our standard certification period. The RICs will generate in your Dashboard for your submission when applicable, including for all new studies and modifications adding study staff. RICs are reviewed and processed by MHS Compliance. Incomplete RICs may also result in delays of IRB approvals. All researchers, regardless of MetroHealth employment status, are required to complete their RICs. Please review our RIC FAQs [[Research Initiated Certification \(RIC\) FAQs](#)] for additional information.

If you are joining MetroHealth for research from another institution and have already completed a COI at your home institution, please contact [compliance@metrohealth.org](mailto:compliance@metrohealth.org) as we may be able to utilize that COI to avoid duplicating efforts.

Please plan ahead to avoid difficulties for yourself and others on your studies. Please contact the Ethics and Compliance Department at [compliance@metrohealth.org](mailto:compliance@metrohealth.org) with any questions.