

Getting Started with the MetroHealth System Institutional Review Board

HRP 602

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. Research Initiated Certification (RIC) and Conflict of Interest (COI)

NOTE: The MetroHealth eIRB Registration, CREC Registration and COI/RIC certifications are three (3) separate steps.

MetroHealth System (MHS) eIRB Registration

FOR QUESTIONS REGARDING eIRB ACCOUNT CREATION ONLY:

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

Enter the MetroHealth IRB website. <https://irb.corp.ent.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 Conflict-of-Interest system, CONI, 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.

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.

A. Initial Certification

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

B. To Register with CITI Program

Go to the CITI online education program to register. 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**,
Good Clinical Practices (GCP) training is limited to those individuals conducting clinical studies that require GCP training by the sponsor (NIH, DOD, other federal agencies, and/or industry). The IRB will only track NIH/federal agency required GCP training. Any other GCP requirements are to be confirmed by the MHS study team and the sponsor.
If any of the above apply, complete one GCP course. If conducting a clinical trial with investigational drugs or medical devices, select the “**GCP for Clinical Investigations of Drugs and Devices (FDA)**.” The
- **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.”

C. To Begin Coursework

- Step 1: If you are not already logged into 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. GCP is required for all study team personnel involved with NIH funded clinical trials.

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 are responsible for verifying and updating your CREC completion and expiration dates for the eIRB system. Please email IRBoffice@metrohealth.org to request an update to your CREC completion. Include a copy of your completion certificate with your request.

Please note that the CREC and GCP 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/AffiliatingCWRUCRECPProgram.pdf>. Please email 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 CREC Certification

Every three years, you must earn at least 12 credits to maintain your CREC certification. The CREC system (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.

Email IRBoffice@metrohealth.org to request an update to your CREC completion. Include a copy of your completion certificate with your request.

For more information regarding CREC, including accessing your completion reports, please visit [Continuing Research Education Credit Program](#)

Conflict of Interest and Research Initiated Certifications

The MetroHealth System uses an electronic conflict of interest disclosure system (CONI) to capture and document an investigator's financial interests via an annual Conflict of Interest certification (COI) and study-related Research Initiated Certification (RIC). Each July, investigators (MHS employed and those primarily employed at another institution without a current COI on file) are required to submit an updated COI. All investigators, regardless of primary employment status, are also required to complete an annual COI with CWRU. Additionally, a RIC will generate in your Dashboard for your submission when applicable. RICs are reviewed and processed by MHS Ethics and Compliance (EC) Department. Incomplete RICs may result in delays of IRB approvals. All researchers, regardless of MetroHealth employment status, are required to complete their RICs.

What is a RIC?

RICs ensure that a study team's current system conflict of interest disclosures is accurate and how, if at all, they impact the study and provides greater protections from potential/actual conflicts in research. A RIC automatically generates in two instances:

1. For all study team members when a new study is submitted for review
2. Study modifications that include a new study team member being added

How is a RIC different from an annual COI?

The RIC serves two purposes: 1) confirmation that your COI disclosure certification is still accurate and 2) how, if at all, your interests impact the research study. In addition to reviewing your COI disclosure statement, if you disclose financial interests in CONI, the RIC will ask the following two questions:

- a) Describe how the aims of the present research project(s) overlaps or does not overlap with any of your financial disclosures.
- b) How will you keep your interests and obligations to any outside entity separate from your activities related to this institution and the present research project(s)?

How do I answer the RIC questions if I don't have any interests disclosed? If you don't have any financial interests disclosed or they are unrelated to the research, indicate such. For example: "I don't have any interests" or "N/A".

What if I have a new interest?

The RIC allows you to update/revise your COI disclosure(s) as needed.

What if I have an interest that has a management plan?

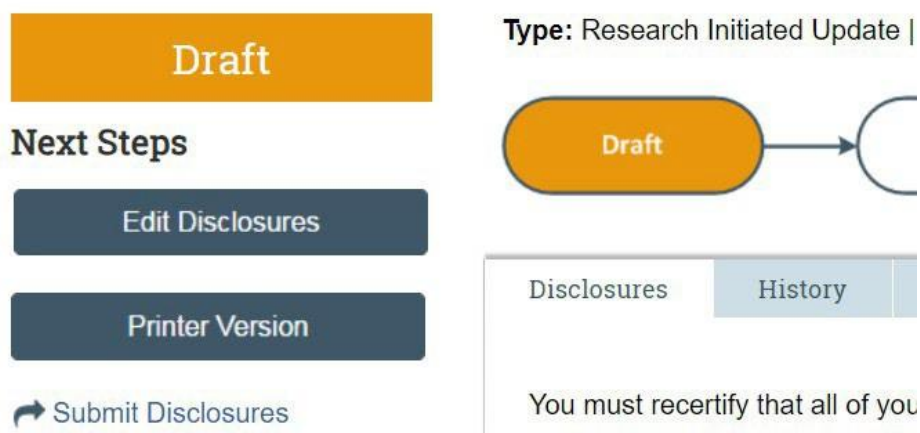
Respond to the questions and indicate that you have a management plan to mitigate any potential or actual conflicts.



Steps to complete a RIC if prompted:

1. Click the hyperlink provided in the email from compliance@metrohealth.org (then advance to step 4) or log into the COI portal (CONI) directly via <https://con1.corp.ent.metrohealth.org/COI>

2. The COI portal can also be accessed from the IRB system by clicking the COI tab in the bar at the top of the page.
3. Once you have clicked into the COI portal, you should see an option in the header labeled "My Disclosures."
4. New disclosures start in the draft state. Once you have clicked on a specific certification, you will have the option to click "Edit Disclosures."
5. After clicking "Edit Disclosures," please complete the form regarding any potential conflicts of interest that you may have for the submission.
6. After completing the form, click "Submit Disclosures."
7. The RIC will either move into "No Review Required" or "Administrative Review."
8. If the status is "No Review Required" or if the RIC is moved into "Review Complete," the RIC is complete.
9. If the RIC moves into "Administrative Review: Response Pending," you will need to check the submission to respond to any questions, clarifications, or requests that the EC staff has regarding your RIC.
10. Once you have addressed all questions or contingencies, EC staff will change the status of the RIC to "Review Complete," at which point you do not need to take additional action for the RIC.



The screenshot displays the MetroHealth COI portal interface. On the left, there is a vertical sidebar with an orange 'Draft' button at the top. Below it, under the heading 'Next Steps', are two dark blue buttons: 'Edit Disclosures' and 'Printer Version'. At the bottom of the sidebar is a blue arrow icon followed by the text 'Submit Disclosures'. The main content area on the right shows 'Type: Research Initiated Update |' at the top. Below this is a diagram with an orange rounded rectangle labeled 'Draft' and an arrow pointing to a partial circle. Underneath the diagram are two tabs: 'Disclosures' (active) and 'History'. At the bottom of the main area, the text 'You must recertify that all of you' is partially visible.

Additional Tips:

- The IRB cannot review submissions until all relevant RICs have been completed.
- Some studies migrated from the previous IRB system will list the RIC status of some study members as "Pending Creation." These COI statements were completed in the previous system and do not need to be re-completed.
- The status of the RICs for a specific submission can be viewed in the IRB system under the "Contacts" tab.
- Any specific questions about potential COIs or issues with CONI are best addressed by the EC Department at compliance@metrohealth.org
- 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 as we may be able to utilize that COI to avoid duplicating efforts.
- Plan to avoid difficulties for yourself and others on your studies. Please contact the EC Department at compliance@metrohealth.org with any questions.