Getting Started with the MetroHealth System 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. Human Subject Protection Training via SpartaLearn (formerly CREC)
3. Continuing Certification
4. Research Initiated Certification (RIC) and Conflict of Interest (COI)

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

MetroHealth System (MHS) eIRB Registration

FOR QUESTIONS REGARDING eIRB ACCOUNT CREATION ONLY:

CONTACT: Skye Carbin

Telephone: **(216) 957 – 2039** **Email:** scarbin@metrohealth.org

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

MetroHealth IRB website. **https://irb.metrohealth.org/eirb**

Request NEW eIRB Account:

To request a NEW eIRB account, fill out the "IRB User Access Request" form IRB User Access Requests (smartsheet.com). Usually, within two business days, your login credentials will be sent to the email provided with next steps. If you do not receive an email following this timeframe, please do not register again. Instead, contact the individual listed above for assistance.

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

Your MetroHealth eIRB profile will NOT be automatically updated by CWRU. The MetroHealth IRB Staff are responsible for updating yourHuman Subject Protection Training expiration dates for the eIRB system. Please email IRBoffice@metrohealth.org to request an update to your Human Subject Protection Training completion. Include a copy of your completion certificate with your request.

Please note that the Human Subject Protection Training and GCP training is good for 3 years.

What if I completed CITI Program at another institution? If your Human Subject Protection 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: AffiliatingCWRUCRECProgram.pdf Please email spartalearn@case.edu for any questions you have about merging courses as well as if there are any required CWRU courses that you need to complete.

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, 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 have an IRB account but cannot access the system, contact the IRB staff for a password reset.

CWRU's SpartaLearn Registration: Completion of CITI Courses

The purpose of Case Western Reserve University's (CWRU's) Human Subject Protection Program is to provide documented training on the protection of human participants in research that is conducted at affiliated institutions. This is achieved via SpartaLearn. For persons just entering SpartaLearn, 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 please email spartalearn@case.edu

A. Register with SpartaLearn:

If you are not already logged into https://spartalearn.case.edu/ do so now. Instructions for access is found here: HRP-Initial-Certification-Directions

B. 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" will appear. Select this. Click "Continue to Step 2."

Step 2: Enter your name, primary 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 "**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.

  NOTE: 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

- **You are required to complete one GCP course ONLY IF the study you are part of is federally funded (e.g., NIH).** If conducting a clinical trial with investigational drugs or medical devices, select the "GCP for Clinical Investigations of Drugs and Devices (FDA)
- **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 SpartaLearn 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. After Completion of CITI modules:

Once you have successfully completed the training, CITI will notify CWRU directly. Information will be downloaded, and an 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.

Continuing Human Subject Protection Certification

Every three years, you must earn at least 12 credits to maintain your Human Subject Protection Training certification. The SpartaLearn system will send an automated email reminder directly to you 30 days before your certificate expires. **You will not be sent reminders from the MetroHealth eIRB system to do this.** Expired Human Subject Protection Training 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 with IRB approvals. Plan ahead to avoid difficulties for yourself and others on your studies.

Email IRBoffice@metrohealth.org to request an update to your Human Subject Protection expiration. Include a copy of your completion certificate with your request.

For more information regarding Human Subject Protection Training, including accessing your completion reports, please visit SpartaLearn ORTM main page: https://case.edu/research/training/spartalearn

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 C W R U . Additionally, 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 instance s:

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 accurateand 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://coni.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.

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.