

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 Research Protection Training via [SpartaLearn](#)
3. Conflict of Interest (COI) and Research Initiated Certification (RIC)

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.

MetroHealth IRB website. <https://irb.metrohealth.org/eirb>

Request NEW eIRB Account:

To request a NEW eIRB account, complete 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 creation. The system will note that your password has expired and may prompt you to change it.

IMPORTANT: Your MetroHealth eIRB profile will NOT be automatically updated by CWRU.

The MetroHealth IRB is responsible for updating Human Subject Protection Training expiration dates in the eIRB system. To request your training record be updated, please email IRBoffice@metrohealth.org and include a copy of your training completion certificate. 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>

Please note that **Human Subject Protection (HSP) Training and Good Clinical Practice (GCP) Training are valid for three years** and must be renewed every three (3) years to remain current. 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.

What if I completed CITI Program at another institution?

If your Human Subject Protection Training was completed at another institution using the CITI Program, researchers can transfer current* CITI training by affiliating with the HRP certification program in SpartaLearn. Additional training may be required based on institutional requirements and the funding source. Please refer to the following link for instructions regarding merging courses from your previous institution: [View SpartaLearn Affiliation/New User Guide](#).

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 log in, 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 eIRB account but cannot access the system, email irboffice@metrohealth.org to request a password reset.

Human Research Protection Training via [SpartaLearn](#)

The purpose of Case Western Reserve University’s (CWRU) Human Subject Protection Program is to provide documented training for 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 Collaborative Institutional Training Initiative (CITI)

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 are 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.”

Conflict of Interest and Research Initiated Certifications

MetroHealth uses an electronic Conflict of Interest disclosure system (CONI) to document investigators’ financial interests through:

- **Annual Conflict of Interest (COI) Certification**
- **Research Initiated Certification (RIC)**

A RIC confirms that a study team member’s current COI disclosure remains accurate and identifies whether any disclosed financial interests relate to or may affect a specific research study.

When is a RIC generated?

RIC is generated:

1. For all study team members when a new study is submitted for IRB review.
2. When a modification adds a new study team member.

When applicable, the RIC is generated in CONI, and the researcher receives an email with a direct link to complete it. All researchers, regardless of MetroHealth employment status, are required to complete any RIC assigned to them. RICs are reviewed and processed by MetroHealth Ethics and Compliance (EC). **Incomplete RICs may delay IRB review and approval.**

Annual COI Requirements

Investigators who are MetroHealth employees, as well as investigators primarily employed by another institution who do not have a current COI disclosure on file, must complete an annual COI certification. In addition, all investigators, regardless of primary employment status, must comply with applicable annual COI disclosure requirements.

How is RIC different from an annual COI?

The annual COI certification documents an investigator's financial interests generally.

The RIC is study-specific and serves two purposes:

1. Confirms that the investigator's current COI disclosure remains accurate.
2. Identifies whether any disclosed interests relate to or may affect the specific research study.

What if I have a new financial interest?

The RIC allows you to update or revise your COI disclosure when needed.

What if I have an interest covered by a management plan?

Complete the RIC questions and indicate that an approved management plan is in place to address the potential or actual conflict of interest.

Steps to complete RIC if prompted:

Click the link provided in the email from donotreply@conflixis.com and follow the log in instructions. If you have a pending RIC assigned to you, it will be available under the "Open Items" tab. After following all prompts and submitting the form, you will receive a completion notification via email from the system.

If there are further questions regarding your RIC disclosures, EC will reach out directly.

Additional Tips:

The IRB cannot begin its review until all required Research Initiated Certifications (RICs) have been completed. Questions about potential conflicts of interest or issues with the CONI should be directed to the MetroHealth Ethics and Compliance Department at compliance@metrohealth.org.

If you are joining a MetroHealth research study from another institution and have already completed a Conflict of Interest (COI) disclosure at your home institution, please contact compliance@metrohealth.org. MetroHealth may be able to accept your existing COI disclosure and avoid duplication.

To prevent delays in IRB review or study activities, please complete all required COI and RIC requirements promptly. Contact the Ethics and Compliance Department at compliance@metrohealth.org with any questions.