Clinical Research Preparation and Paperwork Guide

FIRST STEPS - can be done without a mentor

All clinical research will require some training through the Collaborative Institutional Training Initiative (CITI) Program. Human Subjects Protection and Responsible Conduct of Research training will be required for all clinical research, and some clinical research will also require Good Clinical Practice training.

1. Go to www.citiprogram.org and click on the Register button in the top right of the screen.
2. You should be taken to a 7-step registration screen. For step 1, enter University of Rochester into the text box. Click continue to Step 2.
3. Complete Registration Steps 2-6 as prompted. In Step 5, do NOT elect to receive CEUs for course completion. Continue to the instructions on the next page for selecting/adding training courses.
4. In the last steps of Registration (or if you are adding courses from your home page after you have created an account), you will be prompted to select the courses you need to take.

5. Further options will become available after your courses have been selected.

A. For Human Subjects Protection

Under Initial Certification Program, select...
- Group 1: Greater Than Minimal Risk (Biomedical) if you will be working with a URMC department affiliated with medicine. This is the most comprehensive/widely applicable training that enables work/research applications in drugs, biologics, supplements, devices, or medical procedures.
- Group 2: Greater Than Minimal Risk (Behavioral) if you will be working in psychology or public health.

B. For Responsible Conduct of Research

Select the “UR Undergraduate Students” option.

C. For Good Clinical Practice

Select Good Clinical Practice - Basic Course.
6. From your new CITI home page, you can access your selected trainings. You can add or remove courses as needed using the “My Learner Tools for University of Rochester” links.

All clinical research will require HIPAA training and Mandatory In-Service Training.

**HIPAA Training** can be completed by watching this video (and/or reading this transcript) and then filling out this form. PRINT AND SAVE THIS FORM, as it will need to be given to your future PI or department administrator as proof of training completion. Alternatively, if you have a MyPath account through student employment, you can search for and complete HIPAA training there.

**Mandatory In-Service Training** can currently only be completed through MyPath. If you don’t have a MyPath account, this will training will need to be arranged through a hosting department after connecting with a mentor.

**POTENTIAL NEXT STEPS - require a mentor**

**Complete the SMD Internship Form for URMC Unpaid Interns**

If you are working as an unpaid or for-credit intern in the medical center (URMC-affiliated labs), the SMD Internships and Shadowing application must be completed. The application must be submitted by the department hosting your research—ask your PI and department administrator to fill this in with you. You will need to provide the following information to your department to complete the form.

As part of the SMD Internships and Shadowing form, you will need to conduct research at U of R. I (Teresa Long) am happy to sign as your witness.

If you will be interacting directly with human subjects (rather than just their data), you will need to submit your immunization records, including a recent flu shot and tuberculosis (TB/PPD) test (within the past year), and get a UHS health assessment completed. Your hosting department will need to arrange the health assessment for you through UHS. To do so, the Department/lab Administrators should call Barb Tripp at 275-1155 to register you with UHS. Additional paperwork to sign regarding immunizations may be sent to your PI after completing the SMD Internships and Shadowing Form.

**Create an Active Directory (AD) Account at URMC for computer terminal and patient data system access**

If you are going to need access to a URMC computer OR patient data systems like eRecord, each department has an administrator that must request an AD account for you. Ask your PI who this person is for their department. New account requests can be submitted online by following the instructions posted here (only administrators can access ADTools). The administrator may have to answer these follow-up questions:

1. Describe what business function the student will be serving at URMC and Affiliates. (Intern)
2. Do you have a process for this user to complete URMC HIPAA training (if needed)?
3. What applications/network resources will this user need access to? Is eRecord access required? For how long (set date range or indefinite)?
4. Will this user be using a URMC issued computer or a personal computer? Encryption services can be provided for personal devices.

Contact person for AD account issues: Katie_Seidenberg@URMC.Rochester.edu or URMCAccountRequests@URMC.Rochester.edu
**Requesting eRecord Access and Training to view and/or enter patient data**

If (and ONLY IF) your project requires access to patient data through eRecord, get started requesting access with your PI as early as possible. This process can be lengthy, and you will need a URMC AD account.

1. Have your PI submit an eRecord access request form by following the links for visiting students under the “Student” section on this website.
2. Once access is approved, complete eLearning training online modules provided. If you are having trouble with logins or access, contact the ISD Help Desk at 585-275-3200.
3. eRecord training requires an in-person component hosted in Rochester Tech Park. You can complete this in-person session after the online eLearning training is done. However, it is only available on certain dates. Passing the proficiency exam and these trainings will grant you an eRecord UserID and Password. Your PI can request this training for you through Sharepoint. See this website for information and links.

**Get added to study protocols as needed**

If your project is on an IRB protocol (ask your PI), your PI must add you to that project through a staff modification form. This process can only be completed by your PI or project coordinator.

Be sure to ask your PI about other trainings or protocols you need to follow and/or complete! Requirements are dependent on lab, project, and skills used.