Instructions for Registering and Completing Human Subject Protection & Good Clinical Practice Training

This document includes instructions for:

A. Registering for a Collaborative Institutional Training Initiative (CITI) account
B. Affiliating with Another institution
C. Selecting and Completing a Training Course
D. Finding an Active/Refresher Course
E. Adding a Training Course
F. Finding Course Completion Documentation
G. Updating your Profile
H. Updating your Continuing Education (CE) Status

Already completed training via CITI for another institution? Follow the instructions beginning on page 4 for affiliating with another institution.

Already completed training via CITI for another role related to the University of Rochester? If you have completed training for another role/position within the University (e.g., animal welfare training), please do not create a new (duplicate) account to complete additional training. Contact Kelly Unsworth or Janice Taylor for assistance in accessing your existing CITI account.

Need to complete refresher training? Once a user has completed training, CITI programming automatically registers users for refresher training approximately 90 days prior to training expiration. If you are attempting to complete refresher training within the 90-day expiration window, follow the instructions for finding an active/refresher course. If you would like to complete the refresher training prior to the 90-day expiration window, CITI will need to add the refresher course to your curriculum manually; please contact CITI directly to have the refresher course added to your curriculum.

Unable to access the website or log in? The CITI website has been tested and verified to work on the following internet browsers: Chrome, Safari, Edge, and Firefox. Utilizing Internet Explorer to access the website is not recommended.

If you have any questions about registering for CITI or completing this training, please contact Kelly Unsworth or Janice Taylor.

A. Registering for a CITI Account

1. Go to the Collaborative Institutional Training Initiative (CITI) webpage at www.citiprogram.org and click on ‘Register’ (in the upper right corner).

2. Registration Step 1: Enter the University of Rochester (UR) in the textbox to identify your affiliated organization and select the checkbox to agree to the Terms of Service and Privacy Policy. (Do not select ‘Log in Through My Institution’; the single sign-on option is not available for UR faculty/staff/students.)
   • After agreeing to the Terms of Service and Privacy Policy, select the checkbox to affirm that you are affiliated with the University of Rochester.
   • After affirming your affiliation, click ‘Continue to Create Your CITI Program Username/Password’.
3. Complete the remaining registration steps as prompted, clicking ‘Continue’ to proceed through each step. Note:
   - All new users will be directed to complete a ‘Member Profile’ (generic to CITI) and an ‘Institutional Profile’ (specific to the University of Rochester).
     - Within the ‘Member Profile’, users will be asked to identify a primary/preferred and secondary email address. **UR faculty/staff/students are strongly encouraged to enter their UR email address as the primary/preferred email.** All CITI notifications concerning training renewal/expiration are sent to the primary/preferred email. Entering a personal email address (e.g., Gmail, Yahoo, or Hotmail address) into this field can result in overlooking important reminder emails from CITI. **Personal email accounts should be entered as a ‘secondary email’** (doing so will facilitate access to CITI when/if faculty/staff/students leave the UR).
     - Within the ‘Institutional Profile’, all UR faculty/staff/students **MUST enter an accurate UR email address in the ‘institutional email’ field** to facilitate access to the University’s Click IRB module (within the Integrated Online Research Administration [IORA] system). If the information provided here is not accurate (e.g., a personal email address is entered instead of UR email address or a typo is included within a UR email address), the integration will not function properly. **All non-UR individuals completing CITI training on behalf of a UR collaboration may enter their personal email in the ‘institutional email’ field.**
   - If you receive a prompt that indicates your email address is already in the system, please contact CITI directly at 888-529-5929 to retrieve your username and password. If your existing account was created through another institution, follow the instructions provided below to **affiliate your existing account with the University of Rochester.**
   - Users are provided the option of receiving **Continuing Education (CE) credit** for course completion. Should you wish to receive CE credit, you must answer ‘Yes’ when prompted and provide the requested information regarding credits. **Users are responsible for the fees associated with these credits (the University of Rochester does not cover this fee); as such appropriate billing information will need to be provided when prompted.** Additional information about obtaining CEs can be found by clicking on the ‘My CE/CMEs’ link on the horizontal toolbar at the top of the screen or by contacting CITI directly at 888-529-5929. If you wish to change your CE credit status, see the **instructions below.**

4. Once you have completed the registration process, you will be directed to select a course. See the information provided below on **selecting and completing a training course.**

B. **Affiliating with Another Institution**

**NOTE:** The instructions provided below are intended **only** for study team members who have previously completed course through CITI for another institution.
1. Log into your existing CITI account at www.citiprogram.org (creating a new account will not allow you to receive credit for previously completed work). If you need assistance logging in, please contact CITI directly at 888-529-5929 (CITI can help update email addresses and passwords, as necessary).

2. From the landing page, under the ‘Institutional Courses’ heading, click ‘Add Affiliation’.

![Add Affiliation button]

3. Enter the University of Rochester (UR) in the textbox to identify your affiliated organization and select the checkbox to agree to the Terms of Service and Privacy Policy.
   - After agreeing to the Terms of Service and Privacy Policy, select the checkbox to affirm that you are affiliated with the University of Rochester.
   - After affirming your affiliation, click ‘Continue’.

4. Complete the contact and demographic information. For all UR faculty/staff/students, enter your UR email address in the ‘Institutional Email’ field; this is critical for facilitating access to the University’s Research Subject Review Board online review system (the Integrated Online Research Administration [IORA] system and Click IRB). Note: The information collected during this process only applies to your UR Institutional Profile. Once you have completed the affiliation process, it is recommended that you also review and update your Member Profile.

5. Follow the instructions provided below on selecting and completing a training course. Note: Once you are affiliated with the UR and a training course has been selected, CITI’s software will sum the requirements of both the UR and your previous institution to evaluate whether any previously completed modules may be eligible for transfer credit. Transfer credits are based on the type of training required by each institution and each institution’s training expiration procedures. For assistance with this process, contact Kelly Unsworth.
C. Selecting and Completing a Training Course

1. Select the checkbox for each required training curriculum and click ‘Next’.
   - **Human Subject Protection (HSP)** training is required for all research personnel engaged in human subject research (see [OHSP Policy 201 Education Program](#)).
   - **Animal Care and Use** training may be required for research involving laboratory animals (see [University Committee on Animal Resources (UCAR) policies and training information](#)).
   - **Responsible Conduct of Research (RCR)** training is generally required for: 1) undergraduate, graduate and postdoctoral scholars paid from National Science Foundation (NSF) grants; and 2) individuals receiving support from the National Institutes of Health (NIH) via any training, career development award, research education grant and/or dissertation research grant.
   - **Good Clinical Practice (GCP)** training is generally required by most industry-sponsors for research involving an investigational product and by the National Institutes of Health (NIH), when the research meets the definition of a ‘clinical trial’ (see the [NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials](#) for additional information).
   - **Note:** If you are completing training to meet course requirements and are unsure which curriculum to select, please verify with your instructor and/or the course syllabus (training requirements are course dependent).

2. Select the course(s) to complete within each curriculum selected and click ‘Next’. For Human Subject Protection and Good Clinical Practice training:
   - If this is your **first time** completing training, complete one of the courses identified as an ‘Initial Certification Program’, for Human Subject Protection courses, or ‘Basic Course’, for Good Clinical Practice courses.
   - Training courses should be selected based on the type of research being conducted. Generally, faculty/staff/students working on research conducted in the medical center (or one of the medical center’s affiliates) should complete the Biomedical Researcher training within the Human Subject Protection curriculum and, if applicable (as described above), the GCP for Clinical Trials with Drugs & Devices training within the Good Clinical Practice curriculum.
   - Only individuals serving as members of the Research Subjects Review Board and Office for Human Subject Protection staff should complete the IRB Member training within the Human Subject Protection curriculum.
   - If you are prompted to verify your course placement, select the ‘Stage 1’ option if this is your first time completing human subject protection training or ‘Stage 2’ if you are completing refresher training.
   - If you have previously completed training in CITI for another institution and are unsure which course to select, contact [Kelly Unsworth](mailto:).
3. To begin the course, click ‘Start Now’.
   - If you have previously completed coursework for another institution and transfer credits are provided, the course may be listed under the ‘Active Courses’ heading. Once you begin the course, you will only be directed to complete modules that were not required at your previous institution. In the event that credit for all UR-required modules transfers, the course will appear as complete (no further coursework is required).

4. You will be prompted to complete an ‘Assurance Statement’ prior to initiating the training. Once this has been completed, click ‘Start’ adjacent to the first training module to begin the course.

5. Complete all **required** training modules and each respective quiz as prompted.
   - You may start the course, leave it and come back to it at any time. To access the course at a later time, log into CITI and locate the course using the instructions provided below.
   - You may re-review modules and re-take quizzes, if you wish, by selecting ‘Return to Gradebook’ at the bottom of the computer screen. From the module listing, select ‘Review’ adjacent to the module you wish to re-review.
   - Additional **supplemental** modules may be available for researchers to complete. These modules are **optional** and researchers may choose to complete some or all of these modules. The Office for Human Subject Protection recommends that researchers complete modules that correspond with the nature of the research being conducted.
6. Once you have completed the final module, you will receive a notification at the bottom of the screen indicating that you have completed the course.

7. Following course completion:
   - Print or save a copy of your Course Completion Report for your records prior to logging out of CITI (see instructions below). Please provide this documentation to your department administrators, study coordinator or project manager per your study/departmental needs.
   - The University’s Integrated Online Research Administration [IORA]/Click IRB system and will pull course completion data from CITI automatically; you do not need to provide documentation of your training to Office for Human Subject Protection staff. For UR faculty/staff/students completing initial training, approximately 1-2 business days following course completion, you will receive an email confirming creation of your user account in the IORA/Click IRB platform. Once you have received that notice, you may proceed to submit your research for review/approval and/or be added to existing studies.

D. **Finding an Active/Refresher Course**

1. From the landing page, under the ‘Institutional Courses’ heading, click ‘View Courses’ adjacent to the University of Rochester listing. Alternately, select ‘My Courses’ from the horizontal toolbar at the top of the screen and then select ‘View Courses’ adjacent to the University of Rochester listing.

2. Active courses that have not yet been completed will be listed under the ‘Active Courses’ heading. Courses that have not yet been initiated will be listed under the ‘Courses Ready to Begin’ heading. Click ‘Start Now’ or ‘Continue Course’, as appropriate, to enter the course.
E. **Adding a Training Course**

1. Follow the instructions above in [Part D](#) to locate your University of Rochester course listing. Scroll to the bottom of the page to find ‘Learner Tools for University of Rochester’. Select ‘Add a Course’.

   ![Learner Tools for University of Rochester](image)

2. Follow the instructions listed above for [selecting and completing a training course](#).

F. **Finding Course Completion Documentation**

1. Select ‘My Records’ from the horizontal toolbar at the top of the screen.

   ![CITI Program](image)

2. Below the blue ‘Records’ banner, select the University of Rochester from the ‘Show Records for’ dropdown menu and then ‘Show All’ (if not already selected). Select the ‘View-Print-Share’ options for the applicable training record.

   ![University of Rochester Records](image)

3. Select ‘Copy Link’ to share the Completion Report or Completion Certification via hyperlink or ‘View/Print’ to print or save a PDF copy of the Completion Report or Completion Certificate. **Note:** Most sponsors, funding agencies and study monitors will request the Completion Report as this provides more detail than the Completion Certificate.

![Completion Report](image)

G. **Updating Your Profile**
1. From the horizontal toolbar at the top of the screen, click on the down arrow adjacent to your name in the upper right-hand corner and select ‘Profiles’ from the resulting drop-down menu.

2. Scroll down to select the profile that you wish to update (both profiles should be kept up-to-date).
   - The ‘Member Profile’ is generic to CITI. **UR faculty/staff/students are strongly encouraged to enter their UR email address as the primary/preferred email.** All CITI notifications concerning training renewal/expiration are sent to the primary/preferred email. Entering a personal email address (e.g., Gmail, Yahoo, or Hotmail address) into this field can result in overlooking important reminder emails from CITI. **Personal email accounts should be entered as a ‘secondary email’** (doing so will facilitate access to CITI when/if faculty/staff/students leave the UR).
   - An ‘Institutional Profile’ is created each time a user affiliates with a new institution; the information included in the ‘Institutional Profile’ should be consistent with the user’s role within the institution. Locally, the information included within a UR Institutional Profile facilitates the exchange of training-related information from CITI into Integrated Online Research Administration [IORA]/Click IRB system. The integration functions off of the institutional email entered into this field. As such, **all UR faculty/staff/students MUST enter an accurate UR email address in the ‘institutional email’ field.** If the information provided here is not accurate (e.g., a personal email address is entered instead of UR email address or a typo is included within a UR email address), the integration will not function properly. All non-UR individuals completing CITI training on behalf of a UR collaboration may enter their personal email in the ‘institutional email’ field.

3. Select ‘Edit Profile’ adjacent to the profile you wish to update.
4. Update the profile accordingly, completing all required fields (as indicated by the asterisks) and click ‘Update’ to save your changes.

H. **Updating Your CE Status**

1. Select ‘My CE/CMEs’ from the horizontal toolbar at the top of the screen.

2. Update your CE Credit Status by selecting the radial button for either Yes (to receive CE credit) or No (to de-activate CE credits) and click ‘Submit’.

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Please register your interest for CE credits below by checking the “YES” or “NO” dots, and, when applicable, types of credits you wish to earn at bottom of page. Please read texts entered for each option carefully.

- **YES**
  At the start of your course, you will be prompted to click on a “CE Information” page link located at the top of your grade book and to VIEW and ACKNOWLEDGE accreditation and credit designation statements, learning objectives, faculty disclosures, types, number and costs of credits available for your course.

- **NO**
  The CE functionality will not be activated for your course. Credits and units will therefore not be available to you for purchase after you start your course. You can change your preference to “YES” before such time however by clicking on the “CE Credit Status” tab located at the top of your grade book page.

Submit