<u>CITI training:</u>

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What is CITI?

Collaborative Institutional Training Initiative (CITI) certification is an institutional requirement for all personnel engaging in Human Subject Research (HSR). It includes three primary modules that are required by the institution to participate in conducting various types of research: Group 1: Biomedical Research, Group 2: Good Clinical Practice (GCP), and Group 3: Social & Behavioral Research.

Faculty, employees, students and other institutional representatives at UNMC, Nebraska Medicine, CHMC, and UNO are required to complete the Human Subjects Research (HSR) course via <u>CITI</u> if they will be working on a research project that involves human subjects. It takes approximately 1-2 hours to complete a Basic course. The training does not have to be completed in one sitting, but can be spread out over time if needed.

Basic or Refresher?

The Basic course is designed to establish certification and should be taken when:

- No previous CITI training has been completed, or:
- Prior CITI certification has been expired for a period greater than three years

The Refresher course is designed to re-establish certification for three years and should be taken when:

- The Basic course of a particular group has already been taken, and:
- Recertification is required, but has not been expired for a period of three or more years

Course required based on type of research:

Group 1: Biomedical Research – Investigators conducting research about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods must take this course. Types of research:

- Clinical trial using a drug, medical device, technique or other intervention or strategy (including non-physical means, like diet, cognitive therapy, etc.) to diagnose, treat or otherwise study a particular condition or disease.
- Non-clinical biomedical research to study normal or abnormal physical or physiologic processes (for example: gait and balance testing, biomechanical assessments, etc.).
- Research involving medical records or data registries.
- Research involving human biologic materials.

Group 2: Good Clinical Practice (GCP) – Investigators conducting clinical trials funded by NIH, or utilizing an FDA regulated drug, device, or biologic must take this course. A clinical trial is defined as "a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes".

***Investigators conducting these types of trials must also take the Biomedical course (Group 1).

***This GCP course meets the minimum criteria for training identified by some sponsors. (<u>Check to see</u> <u>if your sponsor is listed</u>.) If so, your CITI completion report can be supplied to the sponsor to meet their GCP training requirement.

Group 3: Social & Behavioral – Investigators conducting research performed with intent to study:

- Behaviors, attitudes, and interactions/social processes among and between individuals, groups, and cultures.
- Generally, this category of research has no intent of producing a diagnostic, preventative, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research.
- This course is primarily taken by students at UNO, although it is common for Nursing Program students to be required to take this as well.

Researchers/Students transferring from other institutions:

Please email all completion reports for previously completed CITI training courses to <u>irbora@unmc.edu</u>. CITI courses are unique from institution to institution and transcript comparison will be required. Only the completion report shows the modules required for transcript comparison. Once previous training has been updated, the IRB will determine if any additional training or Refresher courses will be required.

***It is highly recommended that you <u>email the Completion Report</u> prior to beginning the Refresher course.

***Please do not send completion certificates.

Collaborators with UNMC:

Any independent entity collaborating with UNMC for the purposes of research must also complete CITI training as required by the institution. When registering for CITI, please affiliate with UNMC/UNO and do not register as an independent learner.

Logging In:

• The following link will bring the user directly to the login page:

https://www.citiprogram.org/index.cfm?pageID=14&_ga=2.122943883.169356921.1647264634-865754590.1645471379

- If someone has already registered with CITI enter the username and password in the fields provided.
- Ensure that 'LOG IN THROUGH MY ORGANIZATION' is not underlined, as SSO login is not supported by UNO/UNMC.

	C PROGI	F I RAM	
LOG IN	LOG IN THROUGH MY OF	RGANIZATION	REGISTER
	Username	Forgot?	
	Password	Forgot?	
	Log In		

Registering:

This procedure will show what an individual will need to complete when registering for an account. If an individual has not previously registered for CITI, the following steps must be followed:

• When going the <u>CITI page</u>, click the 'Register' button

		TI RAM	
LOG IN	LOG IN THROUGH MY O	RGANIZATION	REGISTER
	Username	Eorgot?	
	Password	Forgot?	
	Log In		
	Username Password Log In	Eorgot?	

• This will take the user to the first step of the process where they will choose their affiliation (UNMC/UNO) and they will agree to the Terms of Service:

CITI PROGRAM				
LOG IN LOG IN THROUGH MY ORGANIZATION	REGISTER			
CITI - Learner Registration Steps: 1 2 3 4				
Select Your Organization Affiliation				
This option is for persons affiliated with a CITI Program subscriber organization. To find your organization, enter its name in the box below, then pick from the list of cho	ices provided. 🥹			
University of Nebraska Medical Center (UNMC/UNO) University of Nebraska Medical Center (UNMC/UNO) only allows the use of a CITI Progra	m username/password for			
 access. You will create this username and password in step 2 of registration. I AGREE to the <u>Terms of Service</u> and <u>Privacy Policy</u> for accessing CITI Program mater I affirm that I am an affiliate of University of Nebraska Medical Center (UNMC/UNO). 	rials.			
Create a CITI Program account				

• Step 2 will require basic user info to be submitted:

ersonal mitormation	
* indicates a required field.	
* First Name	* Last Name
John	Doe
* Email Address	* Verify email address
example@unmc.edu	example@unmc.edu
	d annall address if you have and in see many and an blacked or you have the shifts to
We urge you to provide a second access the first one. If you forget address. Secondary email address	vernail aduress, if you have one, in case messages are blocked or you lose the ability to tyour username or password, you can recover that information using either email Verify secondary email address

• Step 3 requires the user to create their username and password:

CITI - Learner Registration - University of Nebraska Medical Center (UNMC/UNO)
Steps: <u>1</u> 2 3 4
Create your Username and Password
* indicates a required field.
Your username should consist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as "a12b34cd". Once created, your username will be part of the completion report.
* User Name
Your password should consist of 8 to 50 characters. Your password IS case sensitive; "A12B34CD" is not the same as "a12b34cd".
* Password * Verify Password
Please choose a security question and provide an answer that you will remember. NOTE: If you forget your login information, you will have to provide this answer to the security question in order to access your account.
* Security Question
•
* Security Answer
Continue To Step 4

 Step 4 allows users to connect their ORCID if desired, note their country of residence, and opt in to being contacted regarding CITI coursework:

CITI - Learner Registration - University of Nebraska Medical Center (UNMC/UNO)
Steps: <u>1</u> <u>2</u> <u>3</u> <u>4</u>
* indicates a required field.
-
Would you like to connect your ORCID [®] iD to your CITI Program account? 🥹
D Connect your ORCID iD
* Country of Residence
Search for country: Enter full or partial name (e.g., "United States") OR your country's two or three character abbreviation (e.g., "US", "USA"), then pick from the list of choices provided.
United States
* May we contact you to provide information about other courses and services after you complete your CITI Program coursework? ④
Oyes
● No
Finalize Registration

• For the next step the user will choose 'NO':

— Your CE Credit Status —

CITI is pleased to offer CE credits and units for purchase to learners qualifying for CE eligibility while concurrently meeting their institutions training requirements.

CE credits/units for physicians, psychologists, nurses, social workers and other professions allowed to use AMA PRA Category 1 credits for re-certification are available for most CITI courses – please see "Course List" link under the "CE Credits" tab on login page for details.

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

• The next page will require additional user information:

 Please provide the following information requested by University of Nebraska Medical Center (UNMC/UNO). 						
Fields marked with an asterisk (*) are required.						
Language Preference						
English 👻						
Institutional email address *						
We recommend providing an email address issued by University of						
Nebraska Medical Center (UNMC/UNO) or an approved affiliate,						
rather than a personal one like @gmail, @hotmail, etc. This will help						
University of Nebraska Medical Center (UNMC/UNO) officials identify						
your learning records in reports.						
example@unmc.edu						
Verify Institutional email address *						
example@unmc.edu						
Birth Date *						
01/01/1950						
Highest degree *						
BA, BS or BSN						

Employee Number	
Department *	
Role? *	
	-
Address Field 1	
Address Field 2	
Address Field 3	
City	
State.	
state	
Zip/Postal Code	
Country	
Office Phone *	
Home Phone	
Middle Name/Initial *	
Next	

• On the next page of registration, the user will choose the first selection Human Subjects Research, this is the primary choice for most IRB related training modules: ***Note: Other departments may require additional training***

Question 1
Please select a course
This question is required. Choose all that apply.
Human Subjects Research - required for all personnel participating in IRB approved protocols. Responsible Conduct of Researchers (RCR) - required for certain groups (e.g. graduate students, post-doctoral fellows) Export Compliance (EC) Animal Care and Use (ACU) Clinical Trial Billing Compliance Undue Foreign Influence: Risks and Mitigations Biosafety and Security Clinical Research Coordinator (CRC) Embryonic Stem Cell Investigators and Other Study Personnel Laser Safety Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov
Start Over Next

• Question 2 will allow the user to sign up for specific HSR training modules:



- Descriptions of what kind of research each course covers are provided as a part of Question 2, and the rules differentiating Basic from Refresher are also included.
- Multiple courses can be added at the same time by clicking the checkbox for all that apply e.g.: Group 1, Group 2, and Group 3 all need to be completed.

Affiliating with an institution:

Many times, individuals who come to UNMC have completed CITI training under the umbrella of other institutions. Every institution and that institution's training are isolated from view to other entities. Personnel involved with research at UNMC must affiliate their CITI account with UNMC. This allows UNMC to assign training as needed, but UNMC will still not be able to see training completed at other institutions. This action must be initiated by the individual user as their profile will not be visible to the IRB until they are affiliated.

- Have the user log in to their CITI account.
- The homepage is 'My Courses', from this page 'Add Affiliation' appears at the beginning:



• Clicking the 'Add Affiliation' button will provide a search field:

Affiliate with an Institution	n
Home > Profiles > Affiliate with an Institution	
To find your organization, enter its name in the box below, then pick from the list of choices provided. 🥡	
University of Nebraska Medical Center (UNMC/UNO)	
✓ I AGREE to the <u>Terms of Service</u> for accessing CITI Program materials.	
✓ I affirm that I am an affiliate of University of Nebraska Medical Center (UNMC/UNO). <i>i</i>	
Continue	

- When clicking 'Continue' the user will receive a prompt to enter their user information similar to Step 5 of the registration process.
- Another way to complete the Affiliation process is to have the user go to their 'Profiles' in the User settings, and then scrolling down to 'Institutional Profiles' where they can add an affiliation.



Institutional Profiles

Institutional Profiles contain additional data requested by institutions with which you are affiliated, for management and monitoring of your learning activities. To view or edit this information, use one of the Edit Profile buttons below. If an institution with which you are affiliated is not listed, you may want to <u>add an affiliation</u>. If you are no longer associated with a listed institution, you may want to <u>remove an affiliation</u>.

University of Nebraska Medical Center (UNMC/UNO)

Edit Profile

Would you like to affiliate with another Institution?

Add An Affiliation

Adding Courses:

• Select the 'My Courses' tab (the default when first logging into CITI):



Select 'View Courses'



Choose 'Add a Course'

Learner Tools for University of Nebraska Medical Center (UNMC/UNO)

• <u>Add a Course</u>

- <u>Remove a Course</u>
- <u>View Previously Completed Coursework</u>
- Update Institution Profile
- View Instructions Page
- <u>Remove Affiliation</u>
- This will bring the user to the course selection questions as shown in the registration section, where the subject and course will be chosen:





• The selected course will be immediately added to the member's profile

Removing Courses:

• Select the 'My Courses' tab (the default when first logging into CITI):



Select 'View Courses'



• Choose 'Remove a Course':

Learner Tools for University of Nebraska Medical Center (UNMC/UNO)

- Add a Course
- Remove a Course
- <u>View Previously Completed Coursework</u>
- Update Institution Profile
- <u>View Instructions Page</u>
- <u>Remove Affiliation</u>
- 1. Select which course(s) are to be removed.
- 2. Click 'Submit':

Remove	Course	Stage	Completion Report	Completion Date	Expiration Date
	Group 1: Biomedical Research	Basic Course	54471209	Due Now	8 7 4
	Group 2: Good Clinical Practice (GCP)	Basic Course	50143138	Due Now	-
	Group 3: Social & Behavioral Course	Basic Course	52736323	Due Now	-
	Group 5 - Embryonic Stem Cell Investigators and Key Personnel	ESCRO	50143139	Due Now	
	Research & Academic Personnel	Stage 1	54190149	Due Now	-
	Responsible Conduct of Research	RCR	48486181	Due Now	-

• A confirmation page will appear, click 'Submit' to finalize the course removal:

Course	Stage	Completion Report	Completion Date	Expiration Date
Group 3: Social & Behavioral Course	Basic Course	52736323	Due Now	-
Cancel Submit				

Accessing completion reports & certificates:

• Go to the 'M	y Records' tab:		
My Courses	My Records	My CE/CMEs	Support

• The dropdown menu at the top of the page allows you to access all or institution specific records as needed:

Records University of Nebraska Medical Center (UNMC/UNO) (ID 417)					
Show Records for:	University of Nebraska Medical Center (UNMC/UNO) 🔻	Show All			
versity of Ne	All Institutions Institutional Courses University of Nebraska Medical Center (UNMC/UNO)	JO) Records			

• Scroll down to find completed courses by course category, click the 'View-Print-Share' button to access the record:

Group 1: Bio	iroup 1: Biomedical Research									
Group 1: B	Group 1: Biomedical Research									
Stage	Completion Report #	Start Date	Required Modules	Elective Modules	Member's Score	Passing Score	Date Passed	Expiration Date	Gradebook	Completion Record
Stage 2 : Refresher 1 Course (ID: 171079)		29-Jan- 2016	Completed	None	100%	75%	12-Apr- 2016	12-Apr- 2019	View	View-Print- Share
Stage 1 : Basic Course (ID: 171078)		27-Feb- 2019	Completed	None	81%	75%	27-Feb- 2019	26-Feb- 2022	View	View-Print- Share
Stage 2 : Refresher 1 Course (ID: 171079)		09-Feb- 2022	Completed	None	100%	75%	09-Feb- 2022	08-Feb- 2025	View	View-Print- Share

• The record page has four key components, please see below for the description:

Group 1: Biomedical Research					
Name Stage Comp 1 - Basic Course 27-	Detion Date Expiration Date Record ID Feb-2019 26-Feb-2022				
Completion Report	2 Completion Certificate				
Completion Reports are transcripts of your course work, and include all quiz scores. Part 1 shows scores "frozen" at the time you completed and passed the course. Part 2 reflects scores for any subsequent quiz attempts.	Completion Certificates are "diplomas" that reflect course completion, but do not include quiz scores. Certificates are suitable for sharing with persons who do not need to see your quiz results, or posting online.				
3 View / Print Copy Link 🗷	View / Print 4 Copy Link C				

- Completion Report this is a full listing of the course. In addition to an expanded member information section, and dates of completion; the completion report also includes every module contained in a course. Every CITI course is specific to the institution and courses may be similar or quite different between institutions. The completion report is required when sending CITI records to the UNMC IRB that have been taken from a different institution as transcript comparison is necessary. UNMC requires a 60% threshold to be met when comparing another institution's transcript to UNMC's desired coursework.
- 2. Completion Certificates this is a simple certificate that shows the name, course, date of completion, and expiration date of a given CITI training course.
- 3. The View/Print button this will bring up a window showing either the Report or the Certificate, from here it can be viewed, saved as a .pdf, or printed.
- 4. The Copy Link button this will provide a url link that directs to the 'View/Print' page and can be emailed to an IRB to show proof of completion.

Note: it is always best to send a completion report which provides additional information to the IRB

Please contact the UNMC IRB with any questions at irbora@unmc.edu