Research Educational Training Guide

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ROLE and DEFINITIONS

Please review the researcher's role to determine the educational requirements.

External researchers and staff: An external investigator or research staff (not employed by Geisinger or a Geisinger affiliate) working with a Geisinger Principal Investigator assisting with the conducting or reporting of research.

Investigator: The Principal Investigator or program director and any other Senior/Key Personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research (which may include, for example, collaborators and consultants), regardless of research funding source.

Interns (Paid or Unpaid): Individuals who volunteer for the purposes of education or professional interest as part of a formal or informal educational program.

Students: A student (paid or unpaid) who is learning about research under the supervision of a Principal Investigator, while still attending graduate or undergraduate studies at a university.

Volunteer staff: Individuals who volunteer or donate their time or services to a Principal Investigator, usually on a part-time basis, without contemplation of pay.

Research: Any systematic investigation designed to develop or contribute to generalizable knowledge, including all basic, applied and demonstration Research in all fields of knowledge: (a) conducted pursuant to an agreement between Geisinger and a third party; (b) supported by funding that is administered through Geisinger (e.g., through the Office of Sponsored Program, Research Executive Committee, center, institute or department); or (c) requiring review by a Geisinger regulatory body (e.g., the Institutional Review Board).

Who must complete research educational training?

All researchers and their staff, including GCSOM students, "other" students, volunteers, and interns, who are included on an IRB application, research grant or contract submission, except for Participating Clinicians and Administrative Assistants.

When must research educational training be completed?

CITI's research educational training must be completed for all research personnel **PRIOR** to:

- Submitting a new study application or amendment to the IRB
- Adding new investigators and/or study staff to a research study or grant application
- Submitting a research grant application
- Processing of a research grant award notice
- Executing a research sponsored contract

The research educational training must be current. CITI Program training expires three (3) years after the completion date.

What research educational training is required/accepted?

Effective 1/3/17 acceptable research training from the Collaborative Institutional Training Initiative (CITI) (http://about.citiprogram.org/en/homepage/) is required for all Geisinger researchers and research staff. One training option has been developed for human subject researchers and staff. All researchers and staff must first complete a basic training course prior to completion of the refresher course. Courses are valid for three (3) years after the completion date. The available training courses include:

Human Subject & Data Only Researchers & Staff, IRB Members & Staff – Required for researchers and staff conducting human subject research – Modules include:

- CITI Good Clinical Practice Course
- Human Subjects & Data Only Researchers & Staff, IRB Members & Staff
- RCR for Researchers, Research Staff, and Administrators

Please verify that the CITI courses are the correct modules for Geisinger Research.

Is previous CITI research training from another site acceptable?

No, if you are a Geisinger employee or student, intern or volunteer conducting research at Geisinger, you must add "Geisinger" as an affiliate institution in CITI Program.

Please Note--When you affiliate with Geisinger, CITI Program identifies any shared courses between institutions based upon each module's unique ID number. Geisinger accepts any matching courses or modules that are not expired. Geisinger CITI Program courses are valid for three (3) years after the completion date. Courses that do not match must be completed.

What training is required for external investigators and research staff?

External, non-Geisinger collaborators, investigators and other study personnel can only be included as key study personnel (KSP) on GIRB's iRIS study applications when Geisinger has entered into a formal IRB reliance arrangement with an external institution for non-exempt human subjects' research and is serving as the IRB of record for the non-Geisinger institution. The key personnel are required to complete Geisinger's CITI Program courses if the external institution entering into a reliance arrangement with Geisinger does not provide CITI Program training for their research personnel.

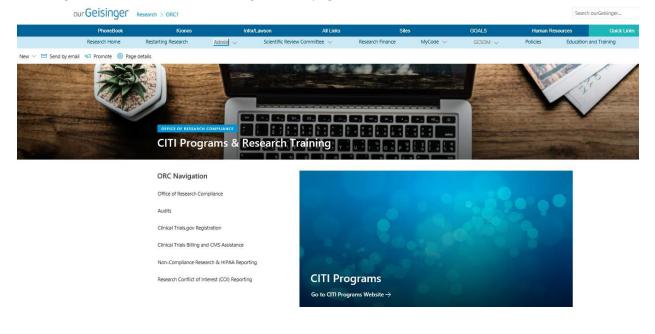
Please Note--Students, volunteers, and interns conducting research at Geisinger are required to follow Geisinger's Research Education and Training Policy (located on Policy Manager under Research ORC) and training requirements listed under the policy. The Non-Geisinger Individuals as Key Study Personnel on IRB Study Applications policy is located on Policy under Research IRB.

How do I access the required CITI Program web site?

CITI Program can be accessed by two different ways: <u>https://about.citiprogram.org/en/homepage/</u> will bring the user to the CITI Program web page which would look similar to this example



or Geisinger user can access CITI Program by using the ORC SharePoint CITI page by https://geisinger.sharepoint.com/sites/ResearchAdmin/SitePages/ORC1.aspx and clicking on the blue CITI Program box to access the CITI Program web page.



How do I update the information or my name in my CITI Program profile?

After logging into your CITI Program profile, **click** on the drop-down menu arrow next to your name at the top right corner of the screen and select "Profiles". This will enable you to update any of profile information except for your username.

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	Profiles		Log Out
	11011100		

Then, **click** "Edit Profile" under Member Profile.

	Profiles	
	Member Profile	
Your member	r profile for the CITI Program includes additional fields and prefer	ences
not shown he	ere. For more information, please <u>view or edit</u> your member profi	le.
Member ID Username Password First Name Last Name	10009 citiadmin9 Demo Tester	
	cory of your past name changes (if any) and email addre r accuracy. If any errors are noted, please report it to	ss changes (if any),
Your changed name in this p	profile will be immediately presented on system display	rs, as well as on

Completion Reports and Completion Certificates that are generated after the change is made.

Please note that CITI Program tracks and logs every name change and will report any name changes that appear to indicate a misrepresentation of identity to the organization(s) sponsoring the account.

Logging into CITI Program as a new user with Geisinger Single Sign On (SSO).

Please Note—Single Sign On (SSO) is available and the required access for users who have a Geisinger email address or Geisinger School of Medicine email address and allows the users to access CITI Program using their Geisinger password.

Access CITI Program homepage by https://www.citiprogram.org.

Click on "Register"



The Trusted Standard in Research, Ethics, and Compliance Training

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.



Over 10 Million Course Completions

The registration screen will look similar to the screen below.



LOG IN LOG IN THROUGH MY INSTITUTION

REGISTER

English •

 CTTI - Learner Registration

 Steps:
 1
 2
 3
 4
 5
 6
 7

 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 choices provided.
 9

Independent Learner Registration

Use this option if you are paying for your courses. This option is for persons not affiliated with a CITI Program subscriber organization, or who require content that their organization does not provide. Fees apply. Credit card payment with American Express, Discover, MasterCard or Visa is required. Checks are not accepted.

or

□ I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials.

Need Help? Support Center

Under "Select Yo	ur Organization Affiliation", type "Geisinger (SSO)"
	English •
	LOG IN LOG IN THROUGH MY INSTITUTION REGISTER
	CITI - Learner Registration
	Steps: 1 2 3 4 5 6 7
	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 choices provided. 🥹
\langle	Geisinger (SSO) ×
	Geisinger allows the use of a CITI Program username/password or Single Sign On (SSO) for access. Single Sign On (SSO) requires a username and password issued by Geisinger. I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials.
	or
	Independent Learner Registration
	Use this option if you are paying for your courses. This option is for persons not affiliated with a CITI Program subscriber organization, or who require content that their organization does not provide. Fees apply. Credit card payment with American Express, Discover, MasterCard or Visa is required. Checks are not accepted.
	□ I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials.

Click both boxes "I AGREE to the <u>Terms of Service</u> and <u>Privacy Policy</u> for accessing CITI Program materials" and "I affirm that I am an affiliate of Geisinger".

Next **click** "Continue to SSO Login/Instruction".

	CITI - Learner Registration	
	Steps: 1 2 3 4 5 6 7	
	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 choices provided.	
	Gelsinger (SSO)	
	Geisinger allows the use of a CITI Program username/password or Single Sign On (SSO) for access.	
	Single Sign On (SSO) requires a username and password issued by Geisinger.	
	 InGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials. Juffirm that I am an affiliate of Geisinger. 	
	Continue To Create Your CITI Program Username/Password Continue To SSO Login / Instructions	
	or	
	Independent Learner Registration	
	Use this option if you are paying for your courses. This option is for persons not affiliated with a CITI Program subscriber organization, or who require content that their organization does not provide. Fees apply. Credit card payment with American Express, Discover, MasterCard or Visa is required. Checks are not accepted.	
	I AGREE to the <u>Terms of Service</u> and <u>Privacy Policy</u> for accessing CITI Program materials. Need Help? Support Center	
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: "Log In T	Through My Institution".	English
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t "Log In T	<text></text>	English

Click "I don't have a CITI Program account and I need to create an account" **select** "Create a New CITI Program Account".

	CITI PROGRAM	
LOG IN	LOG IN THROUGH MY INSTITUTION	REGISTER
Associate your SS	O account with a CITI Program account	
Please choose an o	ption:	
O I already have a (ITI Program account.	
I don't have a CIT	I Program account and I need to create one.	
Create a new CITI	Program account	
By clicking the butto	on below, you will create a new CITI Program account	
Create A New Ci	TI Program Account	

Need Help? Support Center

Research Education & Training Overview 8.15.23

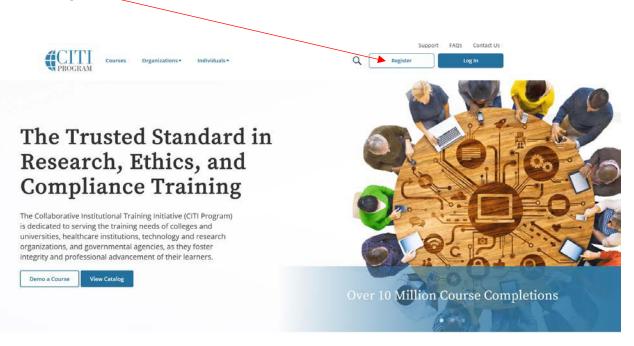
English •

Logging into CITI Program as a new CITI Program external user with Geisinger.

This set of instructions is for users who do not have a Geisinger email address or a Geisinger School of Medicine email address.

Access CITI Program homepage by <u>https://www.citiprogram.org</u>.

Click on "Register"



Under "Select Your Organization Affiliation", in the white box type "Geisinger".

Click both boxes "I AGREE to the <u>Terms of Service</u> and <u>Privacy Policy</u> for accessing CITI Program materials" and "I affirm that I am an affiliate of Geisinger".

Next click "Continue to Create Your CITI Program Username/Password".

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		LOG IN THROUGH MY I	NSTITUTION	REGISTER	
CITI - Learner Re Steps: 1 2 3					
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		with a CITI Program subscriber name in the box below, then pio		choices provided. 🥹	
Geisinger					
Single Sign On (S	50) requires a us Terms of Service	rogram username/password or ername and password issued b and <u>Privacy Policy</u> for accessin Geisinger.	y Geisinger.		
Continue To Cr	eate Your CITI Pi	rogram Username/Password	or	e To SSO Login / Instructions	
		or			
Independent Le	arner Registrati	on			
organization, or w	ho require conte	r your courses. This option is for nt that their organization does n rCard or Visa is required. Check:	ot provide. Fees a	an a	er

Please fill-out the required fields and continue through the registration process. Please enter an email address that matches your home institution or school and must be consistent with the iRIS user account e-mail.

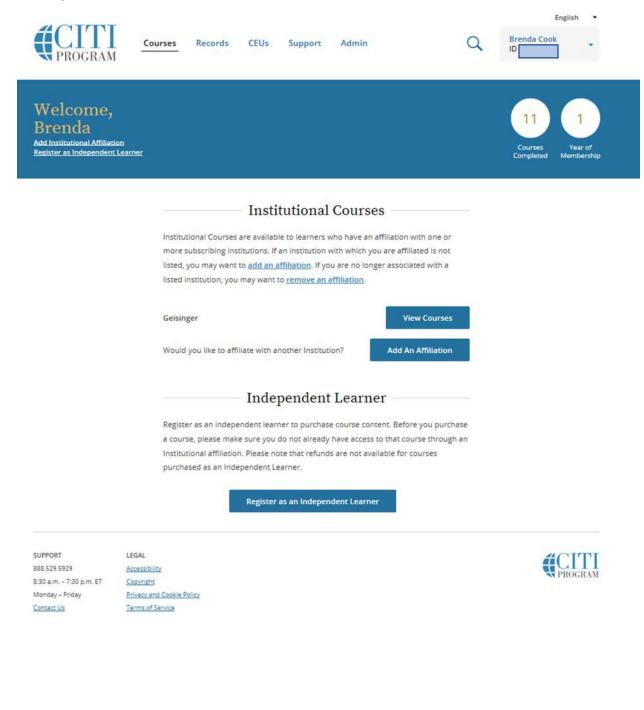
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LOG IN	LOG IN THROUGH MY INSTITUTION	REGISTER
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indicates a required field.		
First Name	* Last Name	
* Email Address	* Verify email address	
	email address, if you have one. in case messages are your username or password, you can recover that ini	
Secondary email address	Verify secondary email address	

.

On the final page of the registration check the circle for "Yes, I conduct or administer research with human
subjects or data".

	Select Curriculum Geisinger
	Question 1
	Do you conduct research in any of the following settings?
	This question is required. Choose all that apply.
	Yes, I conduct or administer research with human subjects or data.
	Start Over Next
A message	will appear stating the registration process is complete. Click on "Finalize Registration".
	LOG IN LOG IN THROUGH MY INSTITUTION REGISTER
	CITI - Learner Registration Welcome to the CITI Program. Your registration with Gelsinger is complete. Finalize Registration
	Need Help? Support Center
pg. 14	Research Education & Training Overview 8.15.23

Users will have a similar screen with their name listed along with the Institutional Courses under "Geisinger".



Affiliating CITI Program courses completed at another institution with Geisinger.

Is previous CITI research training from another site acceptable?

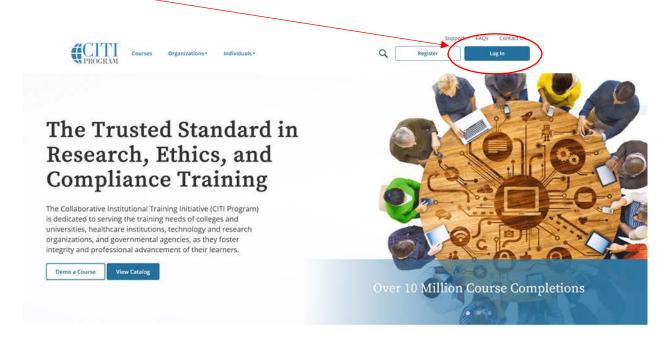
No, if you are a Geisinger employee or student, intern or volunteer conducting research at Geisinger, you must add "Geisinger" as an affiliation in CITI Program.

Please Note--When you affiliate with Geisinger, CITI Program identifies any shared courses between institutions based upon each module's unique ID number. Geisinger accepts any matching courses that are not expired. Geisinger CITI Courses are valid for three (3) years after the completion date of the Basic Course or first refresher course. Courses that do not match must be completed.

How to affiliate with Geisinger in CITI Program.

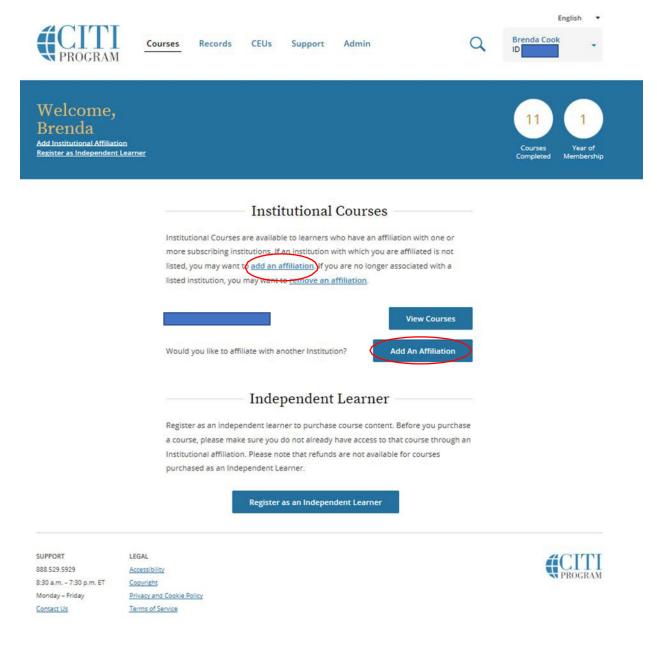
Access CITI Program homepage by https://www.citiprogram.org.

Click on "Log In".



On your home page, there are two links with "add an affiliation".

Click on "add an affiliation".



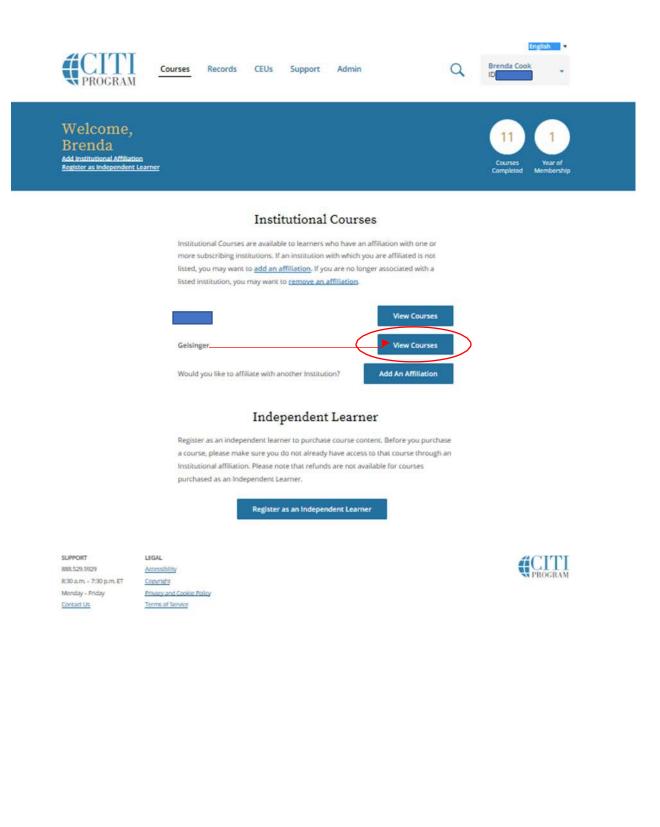
Type "Geisinger" into the box. **Check** the box next to "I AGREE to the Terms of Service for accessing CITI Program materials" and "I affirm that I am an affiliate of Geisinger" and **select** continue.

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CIT PROGRAM	Courses	Records CEUs Support Admin	Q	Brenda Cook
	J	Affiliate with an Institutio	on	
		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. 🕧		
		Geisinger		
		✓ I AGREE to the Terms of Service for accessing CITI Program		
		materials.		
		✓ I affirm that I am an affiliate of Geisinger. ()		
		Continue		
SUPPORT	LEGAL			#CITI
388.529.5929	Accessibility			PROGRAM
	Copyright			
3:30 a.m. – 7:30 p.m. ET				
8:30 a.m. – 7:30 p.m. ET Monday – Friday Contact Us	Privacy and Cookie Po Terms of Service			

Check the circle for "Yes,	I conduct or administer	research with humar	subjects or data".
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S	Select Curriculum Geisinger	
	Question 1	
Do you conduct rese	earch in any of the following settings?	
This question is require	ed. Choose all that apply.	
Yes, I conduct o	or administer research with human subjects or data.	
Start Over	Next	

Your welcome screen will list multiple institutions. **Click** "View Courses" next to Geisinger.



A blue box with "Institution List" will appear. If not already selected, **select** "Geisinger" from the dropdown menu to view Geisinger course information.

Please Note--When you affiliate with Geisinger, CITI Program identifies any shared courses between institutions based upon each module's unique ID number. Geisinger accepts any matching courses that are not expired. Geisinger CITI Courses are valid for three (3) years after the completion date. Courses that do not match must be completed.

COUTSES	Records CEUs Support Admin	English • Q. Brenda Cook ID •	
Welcome, Brenda Add Institutional Affiliation Register as Independent Learner		Courses Completed Vear of Membership	
	Show Courses for: Geisinger	Institution List	
Active C You have no a	OUTSES ctive courses for this Institution.	Learner Tools	
	Ready to Begin ourses ready to begin for this Institution.	Learner Tools	
Complet	ted Courses	Learner Tools	

Single Sign On (SSO) instructions for Geisinger users.

Single Sign On (SSO) is available and <u>the required access for users who have a Geisinger email address or</u> <u>Geisinger School of Medicine email address</u> and allows the users to access CITI Program using their Geisinger password.

Q

Registe

Access CITI Program homepage by https://www.citiprogram.org.

Click on "Log In".

CITTI Courses Organizations• Individuals•

The Trusted Standard in Research, Ethics, and Compliance Training

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.



Support FAQs Contact Us

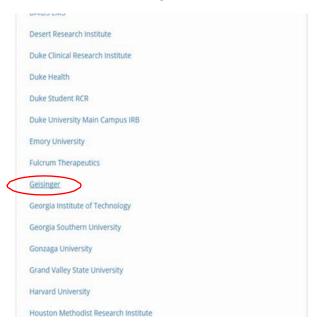
Log In

Over 10 Million Course Completions

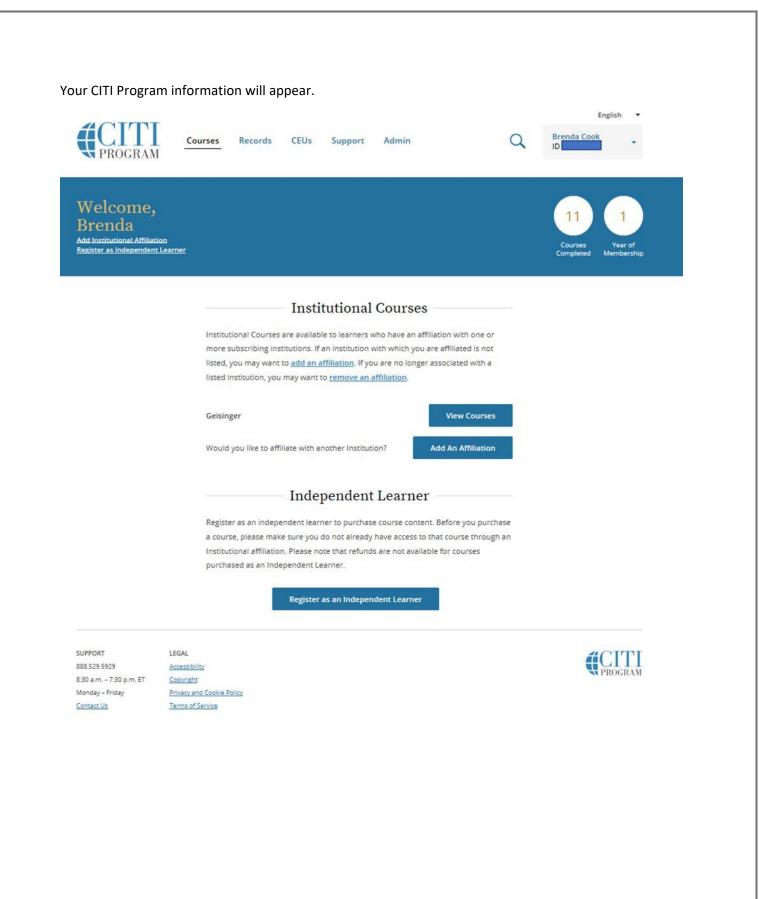
Select "Log In Through My Institution".



The list of institutions will look similar. Scroll through the institutions and select "Geisinger".

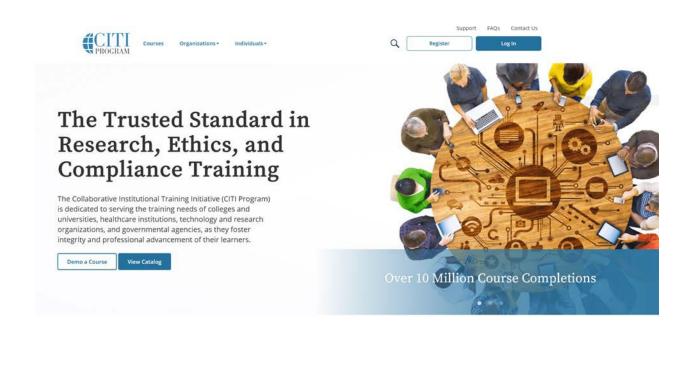


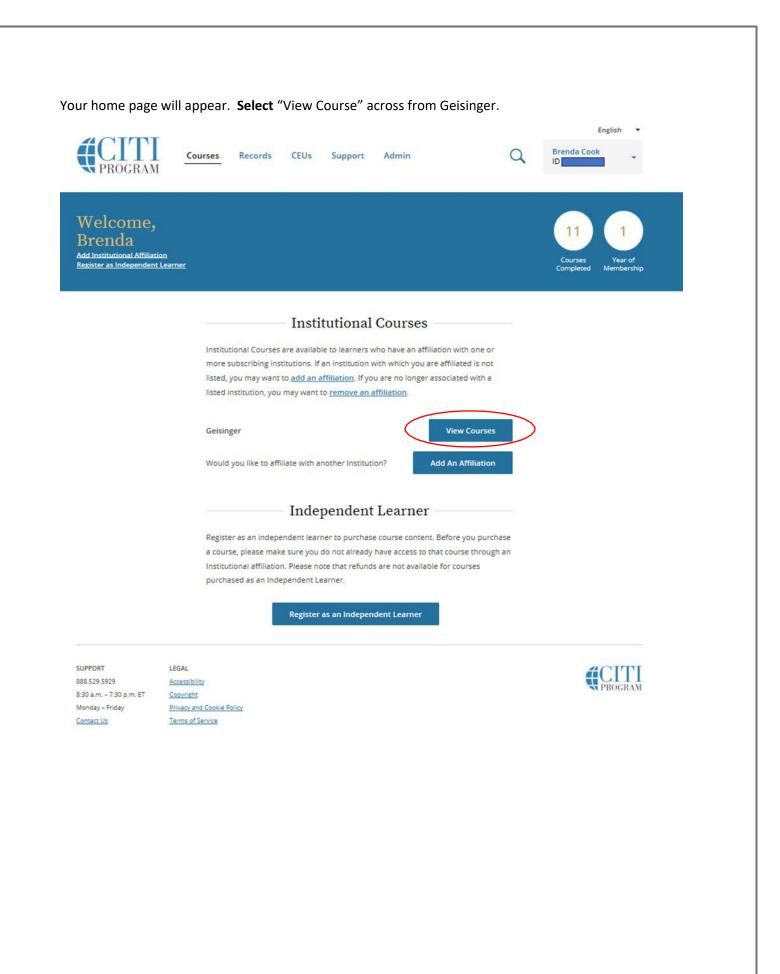
English •



Directions to add courses in CITI Program.

Access CITI Program homepage by <u>https://www.citiprogram.org</u> and log into your account.





The next page will list course that are either completed or available to complete Geisinger. At the bottom of the page, there will be a box. **Select** "Add a Course".

Learner Tools for Geisinger

Add a Course

- <u>Remove a Course</u>
- <u>View Previously Completed Coursework</u>
- <u>Update Institution Profile</u>
- View Instructions Page
- <u>Remove Affiliation</u>

Check the box to add the human subjects or date course module.

Select Curriculum Geisinger	
Question 1	
Do you conduct research in any of the following settings? This question is required. Choose all that apply. Yes, I conduct or administer research with human subjects or data.	
Start Over Next	

Are you able to get Continuing Education credits for CITI Program courses?

Professionals seeking credit for CITI Program courses have the option to select Continuing Education credits at their own expense.

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ere you inten ogram cours		on of receiving Continuing Education L	init (CDU) credit for completed CITI
	offer CE credits a training requirem	nd units for purchase to learners qualifying ents.	for CE eligibility while concurrently meeting
regory 1 credi odule introgu picable, typer res it the start of y pade book an	to for re-certification Please register you to of credito you with your course, you with oto intervent Account	chologists, nurses, social workers and other in an analiable for many OTI courses - with an interest for CE credits below by checking in to earn at bottom of page. Please read to the prompted to clok on a "CE information volve.UDGE accreditation and credit design and costs of credits available for your cost	that availability indicated on course and the "150" or "NO" docs, and, when its entered for each option carefully. • page link located at the top of your non statements, warring objectures.
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Can C/Ti Pro	igram contact yo	u at a later date regarding participatio	n in research surveys? 🗣
7985			2000/01/01/09/07/02
No			
Notsure Au	A me later		
Can CITI Pro	igram contact yo	u at a later date with marketing inform	ution? 4
Yes			

Institutional email address-In order to ensure that CITI Program training downloads into iRIS, users with Geisinger email addresses and Geisinger School of Medicine email address **MUST** use this email in the institutional email position on your CITI Program account. The email address is a matching component between the two systems (CITI Program and iRIS). An automatic download of CITI Program course completion occurs daily into iRIS. Completions with matching email address load automatically into iRIS. All other completions are reviewed by the IRB staff before the training is uploaded.

Are Geisinger CITI Program administrators able to provide training information from other institutions? No, Geisinger CITI Program administration only have access to training certificates for individuals who are affiliated with Geisinger in CITI Program.

Am I able to access CITI Program from a mobile device? Yes, you can access CITI Program through a mobile device.

I am leaving my position. Can I still access my CITI Program completions? Yes, your CITI Program account can be affiliated with other institutions that use CITI Program training for research.

My courses did not all affiliate with Geisinger's CITI Program course modules. Why? The other institution had different CITI Program requirements than Geisinger. Each institution selects which course modules are required within their CITI Program training modules pending the scope of the research conducted at their facilities. Any courses not matching need to be completed for training to be valid under Geisinger.

The courses could be expired. If the CITI Program courses are expired, the completions are no longer valid. Geisinger CITI Program courses are valid for three years after the completion date.

What happens to my account when my courses expire, and I am no longer doing research? Each month, expired research training is reviewed by the ORC staff. Any person with expired research training and is no longer listed on research has their CITI Program account unaffiliated with Geisinger. If the person is listed on a research study later, they must reaffiliate their CITI Program account with Geisinger and complete the expired courses. *If you are listed on an active*

research study, the PI/study team must submit a KSP form to remove you from the research study.

Why doesn't my name and email change happen automatically from Geisinger to CITI Program? Geisinger administrators cannot access the demographic information field for individuals affiliated with Geisinger. Any name or email updates need to be changed by the account holder.

Contact the Office of Research Compliance at Geisinger with any questions by

emailing orc@geisinger.edu or: Phone: 570-214-1635

Office of Research Compliance Staff (ORC):

- Laura Alexander, Research Compliance Analyst (lalexander2@geisinger.edu)
- Brenda Cook, Research Compliance Analyst (bcook@geisinger.edu)
- Mallory Reed, Research Compliance Analyst (mreed16@geisinger.edu)
- Christine Gleave, Manager (cmgleave1@geisinger.edu)