ASU's Guide to Accessing CITI Modules

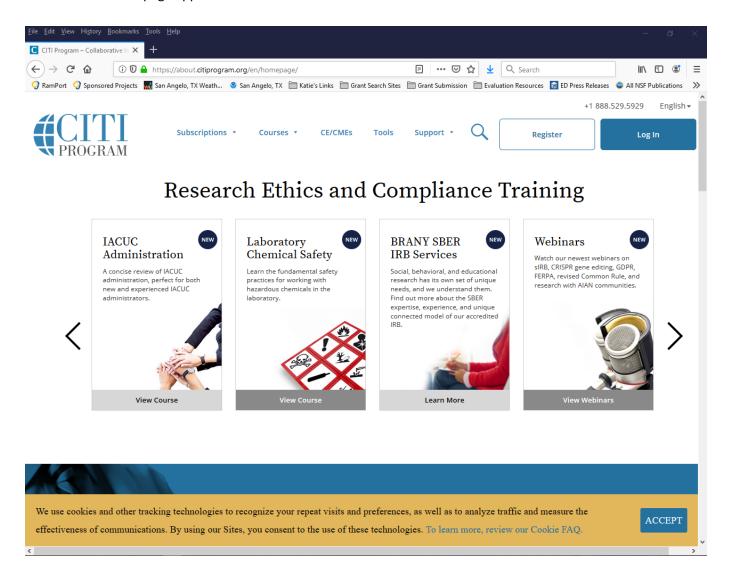
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Logging into the CITI Program for the First Time

Step 1: Go to the CITI Home Page

Type the CITI Home Page URL in your Web browser: https://www.citiprogram.org/

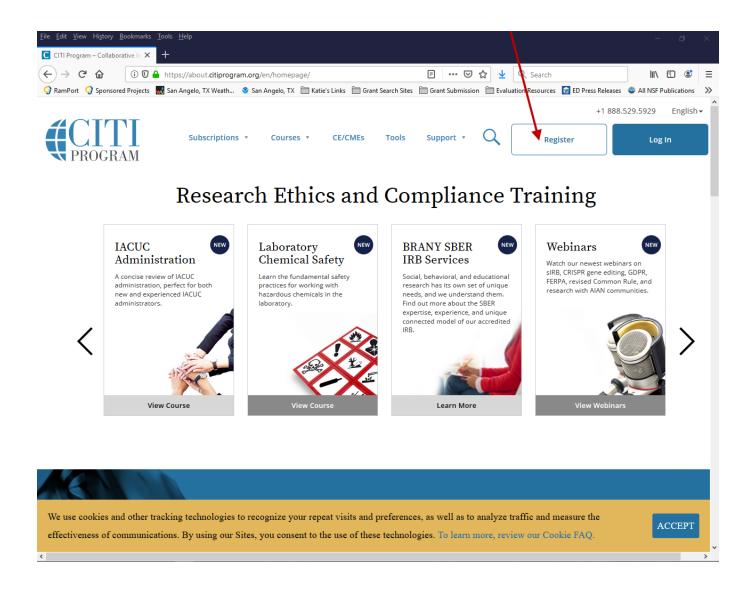
You should see this page appear:



^{*}If you already have a CITI Program account from another institution, please skip this section and follow the instructions on pages 19-22 of this guide to affiliate your account with ASU.

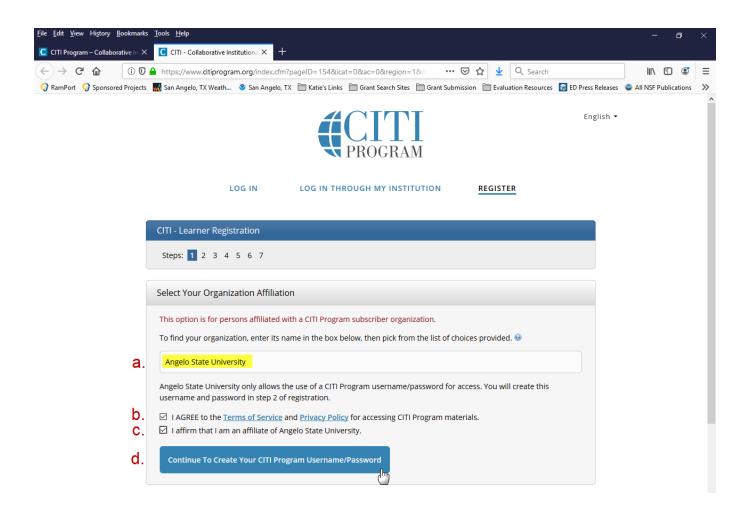
Step 2: Create a new user account

Select the "Register" link on the CITI Program home page:

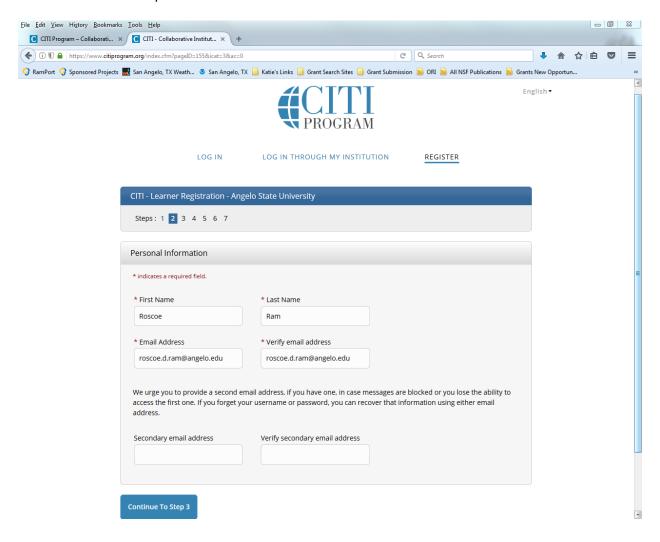


Step 3: Complete registration steps 1-7

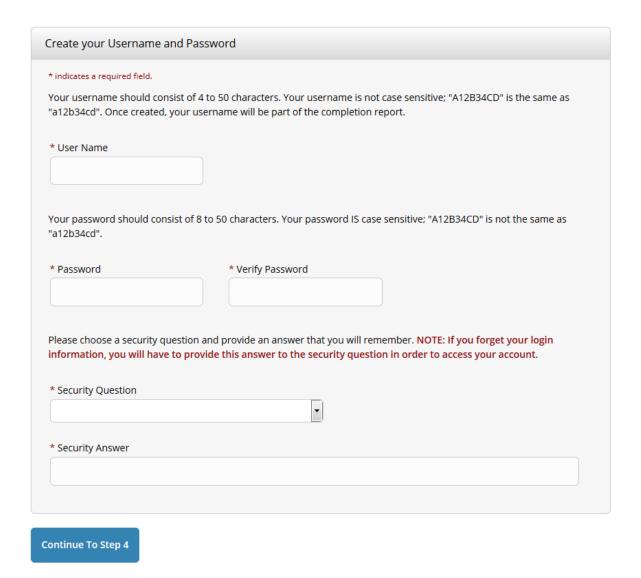
- 1. Select your institution or organization:
 - a. Enter "Angelo State University" under "Select Your Organization Affiliation."
 - b. Review the Terms of Service and Privacy Policy and if you agree, select the checkbox next to the agreement statement.
 - c. After agreeing to the terms of service and privacy policy, an additional checkbox will appear asking you to affirm your institutional affiliation. Confirm that you are "an affiliate of Angelo State University" by selecting the checkbox next to that statement.
 - d. Click on the button that reads "Continue to Create Your CITI Program Username/Password."



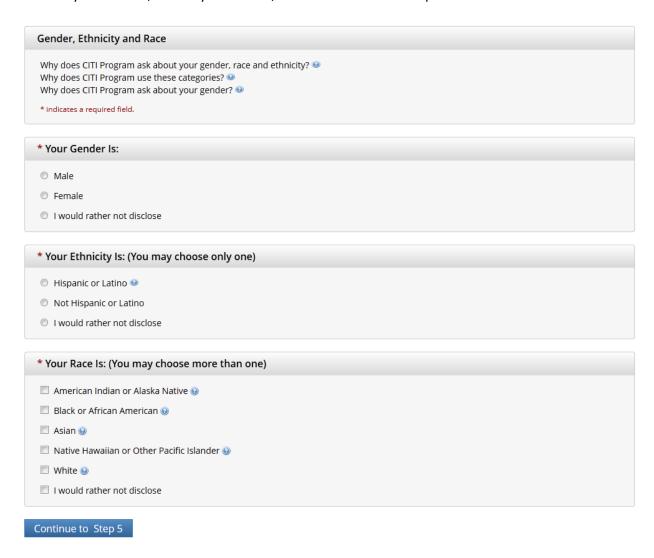
2. Enter your first and last name and your primary and (if desired) secondary e-mail addresses, and then click on "Continue to Step 3."



3. Create your Username and Password, enter your security question and answer, and then continue to step Δ



4. Enter your Gender, Ethnicity and Race*, and then continue to step 5.



^{*}You are welcome to select "I would rather not disclose." CITI collects this information for general research purposes only.

5. Indicate whether you would like to receive Continuing Education Unit (CEU) credit for successfully completed CITI courses. You can change this option at any time, but you must do so *before* you start a course in order to be eligible for CEUs. Some courses do not include an option for CEU credits.

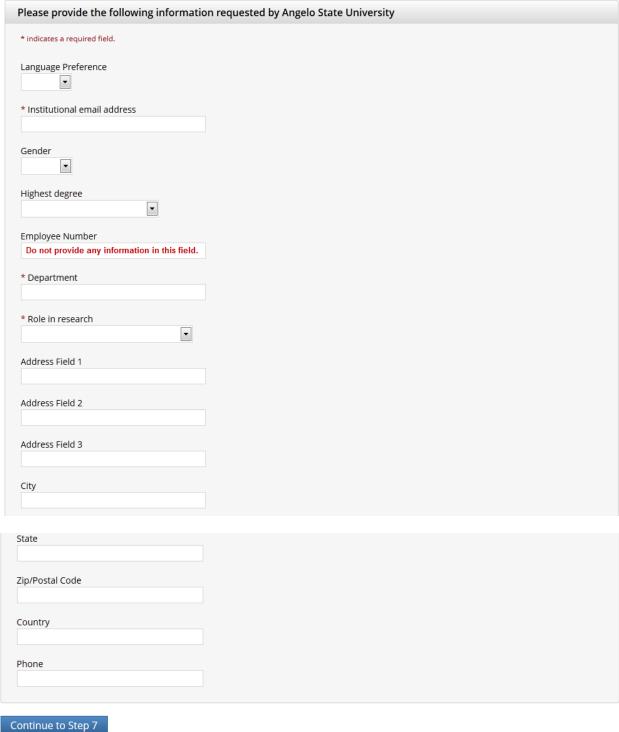
ASU will not cover the additional costs associated with obtaining CEU credits; if you need the CME or CEU credits, you will need to make arrangements to pay for this yourself.

Examples of people who might need CME/CEU credits: physicians, nurses, psychologists, social workers, and/or teachers.

After you have completed this section, continue to step 6.

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program
courses?
If you answer "yes", you will be provided with information before you start a CEU-eligible course about the amount of credit available, information about the course authors, and other required CEU disclosures. This information must be viewed before a course is started in order for you to be eligible to purchase CEU credit after course completion. However, answering "yes" does not obligate you to purchase CEU credits for any course.
If you answer "no", you will not see information about the CEU credits available for courses before you start them or after completing them, and you will be ineligible for CEU credit for these courses. You can change this preference at any time by clicking on a "CEU Information" link or using a "My Profile" link to update your Profile.
If you're not sure, you can change your answer later.
 Yes No Not sure. Ask me later
If you answered "yes", please check all the types of CEU credit that may be of interest. This information allows us to ensure that you receive appropriate Pre- and Post-Course information relevant to the kind(s) of CEU credit that you may request.
 AMA PRA Category 1 Credits Nurses (CNE Credits) Other Psychologists (CEP Credits)
* Can CITI Program contact you at a later date regarding participation in research surveys?
 ○ Yes ○ No ○ Not sure. Ask me later
Continue to Step 6

6. Provide additional information* requested by Angelo State University and continue to step 7.



*Do not enter any information in the field labeled, "Employee Number."

7. Select the Curriculum you will complete*. You may change these items later. Descriptions of each course, including the differences between modules, are provided on pages 12-18 of this guide.

*You may select as many or as few courses as needed to complete your registration and you may leave any of the courses blank.

Once you have selected the courses you want, click on the "Complete Registration" button at the bottom of the page.

Congratulations! You are officially registered to complete CITI training and your registration is associated with Angelo State University.

Selecting Curriculum

The first time you login to CITI, you will want to select the curriculum sections that best fit the type of research or educational activities you will be doing. Do not worry about adding everything at once; you have access to change and/or add curriculum sections at any time in the future.

Most courses take approximately 4-6 hours to complete and may be completed incrementally over a period of several days or weeks. Individual modules within each course usually take 15-30 minutes to complete, and most modules include a quiz. Successful completion of the quizzes is required in order to receive credit for the course.

Once you receive credit for a course, your certificate will be available for you and the appropriate institutional administrators to review and print. If you are a student or a community member working with ASU faculty on a project, the administrator may share your certificate and results with the instructor(s)/supervisor(s) requiring the training. Certificates are valid for the period of time set by the institution, and these vary depending on the course completed; see the individual curriculum descriptions for required renewal schedules.

Note: Significant changes to federal and/or institutional regulations may require more frequent completion of courses/refresher courses.

ASU has subscribed to eight curriculum packages:

- Human Subjects Research
- Health Privacy and Security (HIPS) (to address HIPAA training requirements)
- Good Clinical Practice
- Responsible Conduct of Research
- Laboratory Animal Welfare
- Conflicts of Interest
- Biosafety/Biosecurity
- Laboratory Chemical Safety

The following pages provide more information about these curricula, including a brief description of each package and guidance on which specific course(s) you should select.

Course 1: Human Subjects Research

This course is designed for faculty, staff, and students engaged in research involving human subjects. According to Title 45, Part 46 of the *Code of Federal Regulations*, a human subject is a "living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." (Protection of Human Subjects, 2018, Section 102(e)). It does not apply to the secondary analysis of data sets in which identifiable private information is not included or available.

If you are planning to work with human subjects as defined above, you should complete this course prior to conducting research. ASU requires completion of the refresher courses after three years have lapsed since your initial training. A cumulative score of 80% is required to pass this course.

You may only select <u>one</u> of the following learner groups for this course:

- Biomedical Research Investigators
- Social and Behavioral Research Investigators
- IRB Members
- Students conducting no more than minimal risk research
- Research with data or laboratory specimens ONLY (no direct contact with human subjects)
- Institutional/Signatory Official

Please review the specifications provided by CITI regarding which learner group you should select. **Students:** If you are not sure which group to select, please consult your instructor.

Reference:

Protection of Human Subjects, 45 C.F.R. pt. 46 (2018). Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html



Course 2: Health Information Privacy and Security (HIPS)

Faculty, staff, and students who handle or work with private health information may be required to comply with the requirements of the **Health Information Portability and Accountability Act** (HIPAA). HIPAA requires covered

entities to "protect the privacy and security of health information" (U.S. Department of Health & Human Services, para. 1, n.d.).

If you will handle private health information under the auspices of a covered entity, you should complete this course. This course should be completed at least once every three years, and a cumulative score of 80% is required to pass this course.

Individuals who require continuing education (CE) credits for a professional license or certification (e.g. physicians, psychologists, nurses, and social workers) may pay a small fee to CITI to obtain a CE certificate for completing this course. Please visit the CITI

program's CE page for more information.

You may select as many of the following learner groups for this course as desired:

- Health Information Privacy and Security (HIPS) Course Information for Clinicians
- Health Information Privacy and Security (HIPS) Course Information for Investigators
- Health Information Privacy and Security (HIPS) Course Information for Students or Instructors
- Health Information Privacy and Security (HIPS) Course Information for Fundraisers
- Health Information Privacy and Security (HIPS) Course Information for Marketers
- Federal Educational Rights and Privacy Act (FERPA) [note: this course deals not with health information privacy and security but with information privacy and security in the context of education]

Please review the specifications provided by CITI regarding which learner group you should select. **Students:** If you are not sure which group to select, please consult your instructor.

Reference:

U.S. Department of Health & Human Services. (n.d.). Health Information Privacy (Web page). Retrieved from https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html

Course 3: Good Clinical Practice

This course is designed for those individuals who are involved in FDA covered research activities, including clinical trials of drugs and medical devices, as well as any related research involving other substances and/or devices requiring FDA approval.

It is not likely this course will be necessary for research conducted at ASU; however, because the possibility does exist, the Office of Sponsored Projects (OSP) has made it available. Please contact the OSP to confirm whether you need to take this course if you are unsure about it. For those required to take this course, it should be completed at least once every three years, and a cumulative score of 80% is required to pass it.

You may select as many of the following learner groups for this course as desired:

- Good Clinical Practice, U.S. FDA (Food and Drug Administration) Focus
- Good Clinical Practice for Clinical Trials Involving Medical Devices (international focus)
- Good Clinical Practice for Clinical Trials Involving Investigational Drugs (ICH/international focus)



Course 4: Responsible Conduct of Research (RCR)

The Responsible Conduct of Research (RCR) course provides training in the responsible and ethical conduct of research. It includes modules on research misconduct, data acquisition, management, sharing and ownership, publication practices and responsible authorship, conflicts of interest, human and animal subjects, and working in a collaborative research environment.

Several federal agencies, including the National Institutes of Health and the National Science Foundation, have a requirement that undergraduates, graduate students, and post-docs complete training in the RCR. To be compliant with these requirements, all student/post-doctoral assistants receiving funding from one of these agencies *must* complete RCR training shortly after they have been hired. This course should be completed at least once every three years, and a cumulative score of 80% is required to pass this course.

You may only select one of the following learner groups for this course:

- Biomedical RCR
- Social and Behavioral RCR
- Physical Science RCR
- Humanities RCR
- RCR for Engineers
- RCR for Administrators
- Not at this time [you may change this option at a later date]



Course 5: Laboratory Animal Welfare

Individuals engaged in research covered by the Animal Welfare Act (7 USC, 2131-2159) should complete training in the ethical care and use of animals. Not covered under the Animal Welfare Act are birds, horses not used for research, and livestock intended for use as food or fiber or for research to improve the quality of food or fiber. Livestock used for biomedical research, however, are covered by the Act.



The scope of the research will determine which learner groups each individual must complete, but all faculty, staff, and students involved in Animal Welfare Act-covered research should complete the "Working with the IACUC" course. For individuals conducting multi-year research, the refresher course should be completed every three years, and a cumulative score of 80% is required in order to receive credit.

You may select as many of the following learner groups for this course as desired*:

- Working with the IACUC (required for all lab animal research)
- Essentials for IACUC Members (required for all IACUC members)
- Institutional Official
- Antibody Production
- Aseptic Surgery
- Minimizing Pain and Distress (required for studies with potential to cause "more than momentary pain and distress" in mice or rats)
- Mice Family: Muridae Cricetidae
- Genetically Modified Mice
- Rats Genus: Rattus
- Frogs, Toads, or other Amphibians
- Hamsters Family: Muridae
- Gerbils
- Guinea Pigs
- Rabbits Family: Leporidae
- Ferrets
- Swine
- Fish
- Cattle
- Sheep & Goats
- Wildlife Research
- Refresher Course for Working with Animals in Biomedical Research
- IACUC Member Refresher

^{*}Note: If you are working with one or more of the above listed groups of lab animals, you should select and complete the appropriate family/genus/species-specific elective(s).

Course 6: Conflicts of Interest (COI)

A variety of conflicts of interest may exist when conducting research. Financial conflicts of interest, conflicts of commitment, and other conflicts may influence or appear to influence the conduct and reporting of research activities. This has become such a hot-button issue that federal and state agencies and even elected officials have tightened disclosure rules in recent years. For example, the Public Health Service (PHS), which includes the National Institutes of Health, now requires investigators to complete training on financial conflicts of interest for all investigators *prior to* engaging in any PHS funded research (42 CFR 50).

This short course provides a basic overview of the different types of conflicts of interest, with an emphasis on financial conflicts of interest. Unlike the other CITI courses, it takes approximately one (1) hour to finish, so participants may easily complete this course in one sitting. There are no learner group choices for this course; everyone required to take it enrolls in the same course and completes the same four modules.



Individuals required to complete this course must do so at least once every four (4) years, and a score of 80% or better is required to pass the course.

Note: All faculty, staff, and students who share responsibility for the design, conduct, or reporting of research funded by the Public Health Service (federal) or the Cancer Prevention and Research Institute of Texas (state) must complete this course in accordance with <u>ASU Operating Policy 56.08</u>.

Course 7: Biosafety/Biosecurity (BSS)

Activities and experiments carried out in scientific laboratories may involve interaction and/or contact with any number of potentially biohazardous materials, including bloodborne pathogens, infectious agents, and



recombinant DNA, among others. To comply with the biosafety standards issued by the Occupational Safety and Health Administration and the National Institutes of Health, Angelo State University requires individuals engaged in research or education activities involving potentially biohazardous materials to complete Biological Safety Training, which is provided via Blackboard by the Office of Environmental Health, Safety, and Risk Management (EHSRM).

In certain circumstances, however, the training provided by EHSRM must be supplemented by one or more of the CITI Biosafety/Biosecurity (BSS) courses. Additionally, all members of ASU's Institutional Biosafety Committee (IBC) are required to complete the CITI IBC Member course.

Members of the IBC and other individuals required to complete one of the CITI BSS courses should select one or more of the following applicable learner groups to satisfy the additional biosafety training requirements:

- Biosafety Officer Training
- Basic Biosafety Training
- Animal Biosafety
- OSHA Bloodborne Pathogens
- Emergency and Incident Response to Biohazard Spills and Releases
- NIH Recombinant DNA (rDNA) Guidelines
- OSHA Personal Protective Equipment Training
- Institutional Biosafety Committee Member

Individuals required to complete one or more of these courses must do so at least once every four (4) years, and a score of 80% or better is required to pass each course.

Course 8: Laboratory Chemical Safety

Research and educational activities undertaken in the laboratory carry with them hazards and risks, particularly when using chemicals of any type. It is incumbent on laboratory instructors and managers as well as principal investigators on research projects to model best practices in handling chemicals in the lab. Moreover, these individuals are responsible for ensuring their students, research assistants, and trainees know how to handle chemicals safely.

The Laboratory Chemical Safety course provides the information necessary for faculty, lab managers, and principal investigators to serve as instructors and mentors in laboratory safety. Topics covered include the fundamental concepts behind laboratory chemical safety, hazard identification and risk mitigation strategies, and specific requirements associated with engineering controls and the use of personal protective equipment (PPE).



This course contains only one learner group, so if you are required to complete it, please select the "Laboratory Chemical Safety" option on Question 8 of the Select Curriculum menu.

Individuals required to complete this course must do so at least once every three (3) years, and a score of 80% or better is required to pass the course.

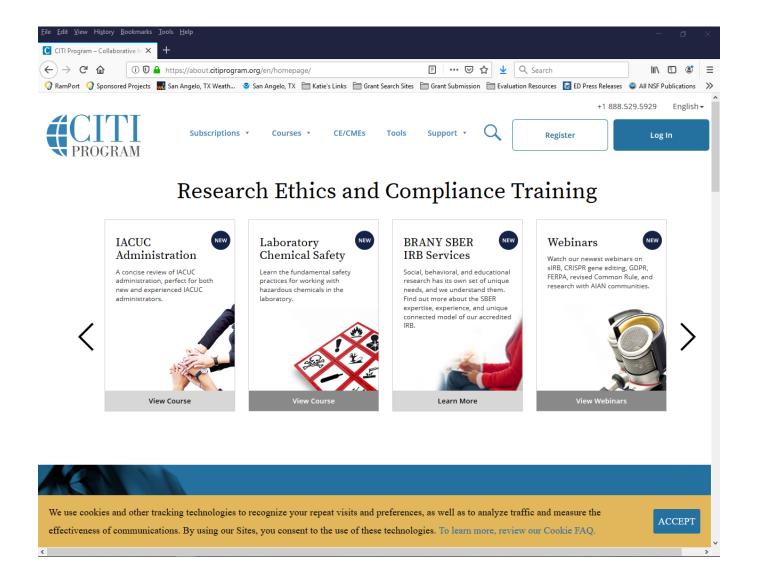
Associating an Existing Account with ASU

If you have completed CITI courses while affiliated with another institution, you can associate your previous coursework with Angelo State University, allowing you to receive credit for work you have already done, provided that the coursework was completed no longer than 2-3 years ago. To do so, follow these steps:

Step 1: Go to the CITI Program Home Page

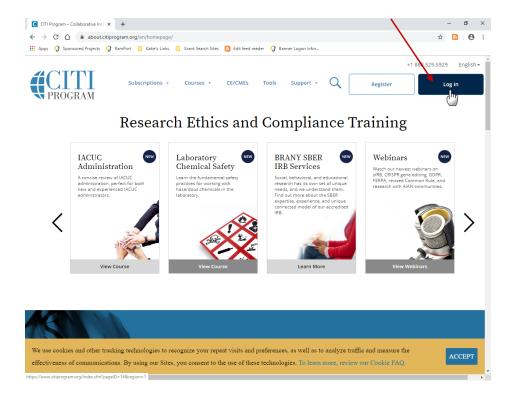
Type the CITI Home Page URL in your Web browser: https://www.citiprogram.org/

You should see this page appear:

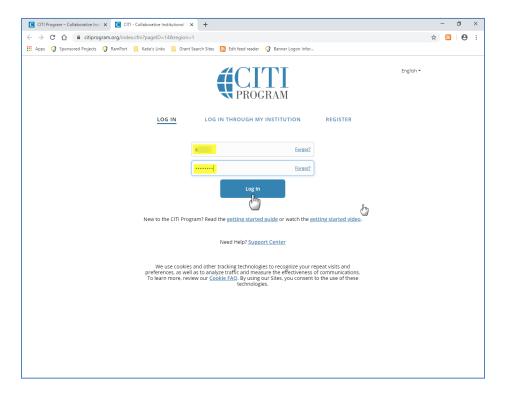


Step 2: Enter Your Username and Password

Select the "Log In" button in the upper right corner:

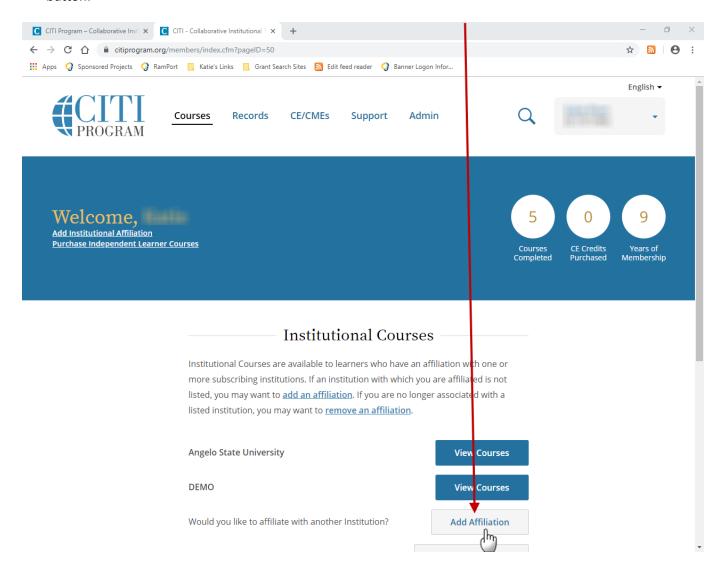


Type your username and password and click on the Log In button:

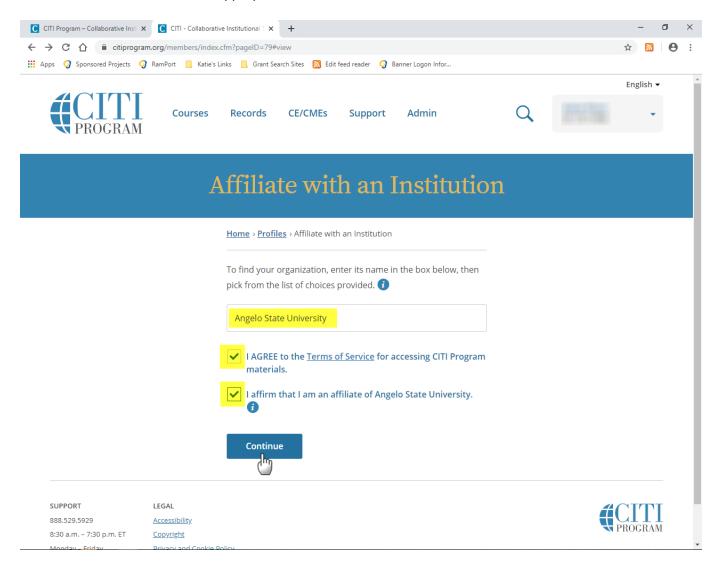


Step 3: Affiliate Your Account with ASU

1. Once you have logged into the CITI system, affiliate your account with ASU by selecting the "Add Affiliation" button:



- 2. Enter "Angelo State University" in the "To find your organization..." box and Select Angelo State University from the list of choices provided.
- 3. Review the Terms of Service and Privacy Policy and if you agree, select the checkbox next to the agreement statement.
- 4. After agreeing to the terms of service and privacy policy, an additional checkbox will appear asking you to affirm your institutional affiliation. Confirm that you are "an affiliate of Angelo State University" by selecting the checkbox next to that statement.
- 5. Click on the button that reads "Continue." After you continue, you'll have the opportunity to provide an ASU email address and select the appropriate curriculum.



Congratulations! Your account is now affiliated with Angelo State University.

Questions or Problems?

If you have any questions or problems with the CITI system, please contact the Office of Research and Sponsored Projects at 325-942-2530 or osp@angelo.edu