CITI Program Manual

For Mahidol University's Staff & Students

Version Date May 30, 2019
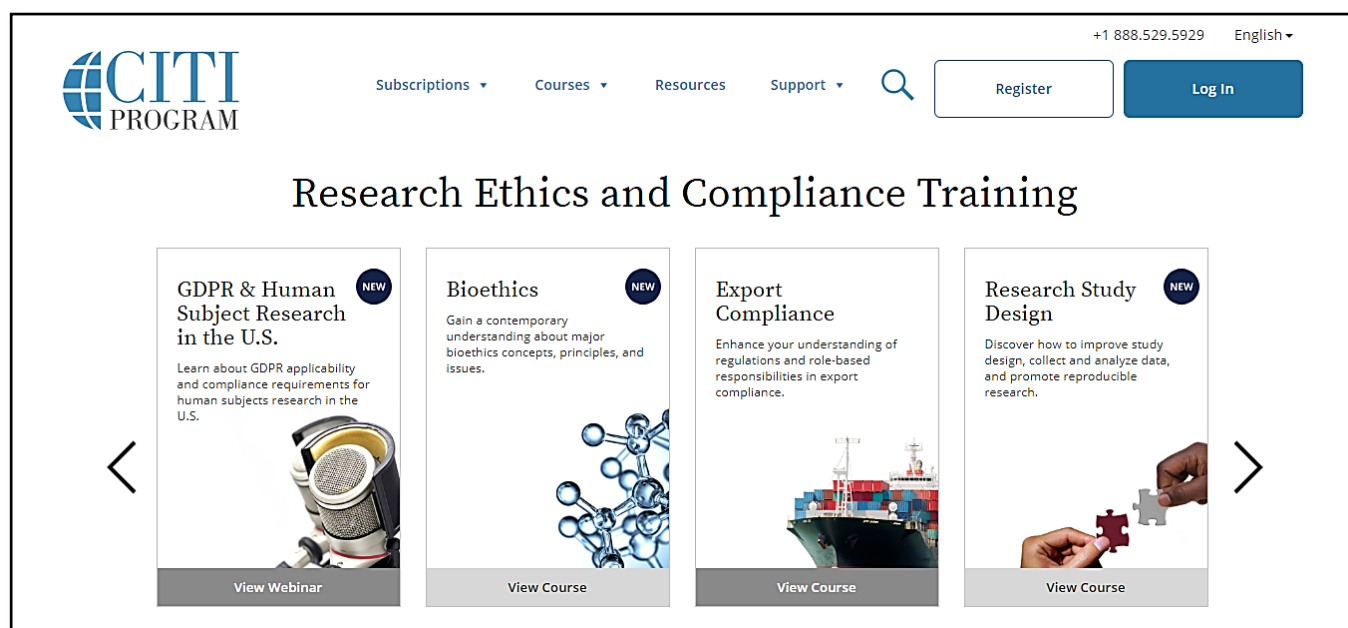
By

MU-CERf

Mahidol University, Center of Ethical Reinforcement for Research

Guide to CITI Program 2019

<u>C</u>ollaborative <u>I</u>nstitutional <u>T</u>raining <u>I</u>nitiative (CITI Program) Collaborative Institutional Training Initiative (CITI Program) is an online training program developed in the year 2000 from collaboration between 10 research institutes/universities in the USA in order to provide a self- study tool for researchers in human subject protection. At the beginning, the content covered only biomedical research but in 2004 the program was developed to cover social and behavioral research. (Human Subjects Research Social and Behavioral Researchers: HSR-SBR course)

At present, the content was developed for another field of research beyond human research such as:-

- ✓ Animal Care and Use (ACU),
- ✓ Biosafety and Biosecurity (BSS),
- ✓ Export Control (EC),
- ✓ Good Clinical Practice (GCP),

- ✓ Information Privacy and Security (IPS),
- ✓ Responsible Conduct of Research (RCR)
- ✓ Conflicts of Interest (COI)

Mahidol, as a national research university, recognized the important of education and training for its researchers in ethical guidelines for responsible research conduct to safeguard human subjects, experimental animal welfare and safety for the environment. To reach this goal, Center of Ethical Reinforcement for Human Research is responsible on behalf of Mahidol University in providing various kinds of education & training for researchers not only hands-on workshop but also online training by subscribing the CITI Training program for foreign faculties and students or as an alternative for ones who prefer self-study.

<u>Modules available are</u>

1. *Human Subject Research (HSR) Series available separately for biomedical research and social-behavioral research. This series were tailored into 9 modules for various kinds of users such as*

   Group 1 Biomedical researchers

   Group 2 Social-Behavioral& Humanities researchers

   Group 3 Clinical Research Center Staff/ Contract research Assistants

   Group 4 IRB Staff: Biomedical panel

   Group 5 IRB Staff: Social-Behavioral panel

   Group 6 Students who conduct biomedical research

   Group 7 Students who conduct social-Behavioral & Humanities research

   Group 8 IRB Members: Biomedical panel

   Group 9 IRB Members: Social-Behavioral& Humanities panel

2. *Good Clinical Practice (GCP) for biomedical researcher who conduct new drug or new medical device development.*

3. *Animal Care and Use (ACU) for animal experimentation.*

4. *Information Privacy and Security (IPS) for using health-related data and digital data*

5. *Responsible Conduct of Research (RCR): data management, authorship, research misconduct, plagiarism*

6. *Conflicts of Interest (COI)*

In each course contains 3 types of modules:

R = Required	E = Elective	S = Supplement

To earn a completion report (Certificate of Completion), learners must

- study all R modules,

- select some of E module to study as indicate, for example 3 out of 9 modules

For S modules are optional and becomes available to learners after R and E modules are completed, to be reviewed on a voluntary basis.

Contents

How to register to use the CITI Program

1. Use Web Browser such as Internet Explorer, Google Chrome, Mozilla Firefox Type

   https://www.citiprogram.org/ at URL and Enter. You will see this page, then select "Register"
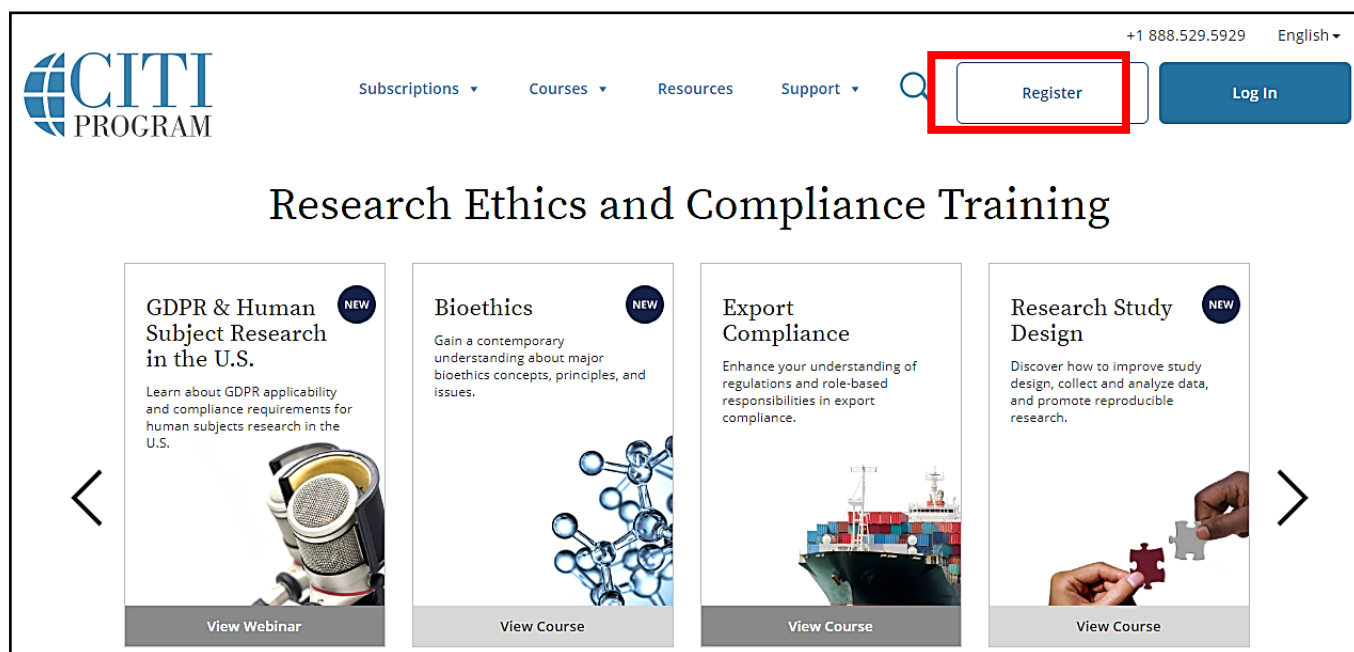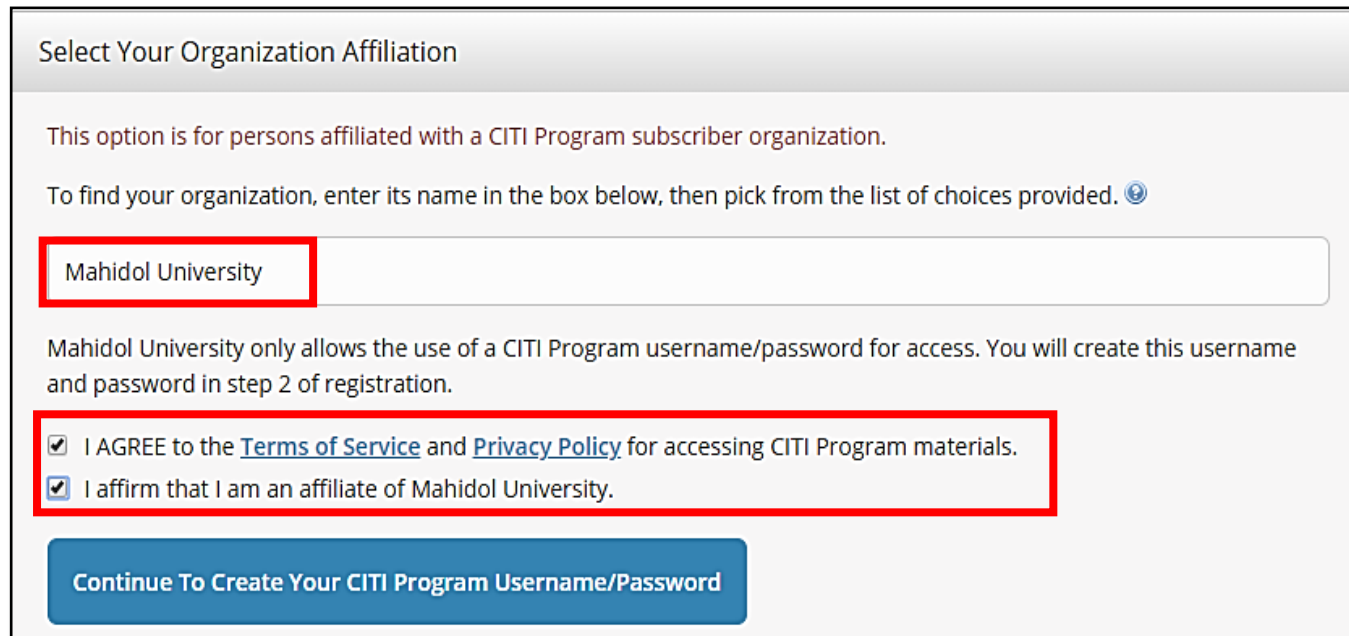

Figure 1

2. The CITI - Learner Registration has 7 steps.

Steps: 1 Select your organization affiliation, type "Mahidol University" in textbox >> Select checkbox >>

Click **Continue to Create Your CITI Program Username/Password**

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. ⓘ

Mahidol University

Mahidol University only allows the use of a CITI Program username/password for access. You will create this username and password in step 2 of registration.

☑ I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials.
☑ I affirm that I am an affiliate of Mahidol University.

Continue To Create Your CITI Program Username/Password

Figure 2

Steps: 2 Personal Information Fill in the textbox as required and Click **Continue to Step 3**

- First Name
- Last Name
- E-Mail Address (must be @mahidol.ac.th)

- Verify E-Mail Address (Verify E-Mail Address@mahidol.ac.th)
- Secondary E-Mail Address
- Verify Secondary E-Mail Address)

      Please be advised that secondary email should not be the same as the first one. If the information cannot be sent through the first email, the second one can be used instead. If you do not have secondary email address……., leave it blank and then click "continue to step 3"

Figure 3

Steps: 3 Create your Username and Password by filling in the textbox and Click **Continue to Step 4**

- User Name
- Password
- Verify Password

- Security Question in case of forget pass word
- Security Answer in case of forget pass word
- Verify Password

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

Your password should consist of 8 to 50 characters. Your password is **case sensitive**: "A12B34CD" is **not** the same as "a12b34cd"

Figure 4

Steps: 4 Country of Residence- type "Thailand" and Click **Continue to Step 5**

* 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.

Continue to Step 5

Figure 5

Steps: 5 Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses? Choose "No." (because CE credit is not the system for Thailand)

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?

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 many CITI courses – with that availability indicated on course and module listings. **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.
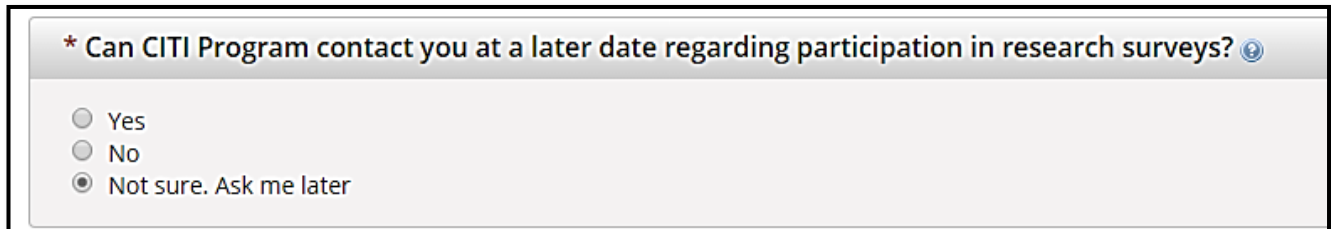
○ Yes

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 grad book page.

◉ No

Figure 6

Can CITI Program contact you at a later date regarding participation in research surveys? Choose according to your own interest. If you click "yes" you may spend some time answering more question before proceed to the next step.
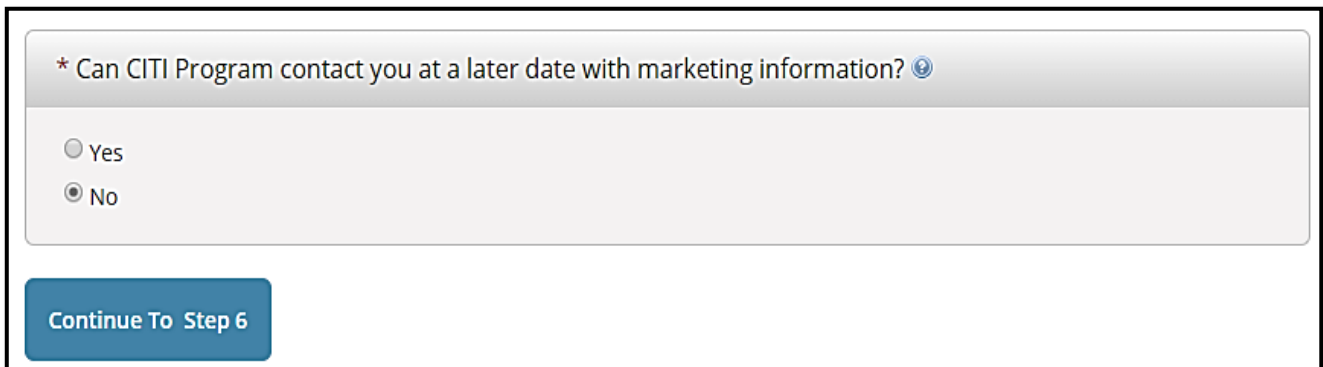

Figure 7

Can CITI Program contact you at a later date with marketing information? Choose as you like and Click **"Continue to Step 6"**

Figure 8

Steps: 6 Please provide the following information and Click **Continue to Step 7**

- Language Preference: English

- Institutional email address: …..@mahidol.ac.th

- Gender : Female or Male

- Highest degree …………….

- Employee Number: no need to fill

- Department………………..

- Role in research ………………….

- Address Field 1: your affiliation such as department, faculty

- Address Field 2: the department office building

- Address Field 3: Mahidol University, 999 Phuttamonthon 4 Road, Salaya,

- City : Nakhon Pathom

- State : no need to fill

- Zip/Postal Code : 73170

- Country : Thailand

- Phone: +662 XXX-XXXX or +6681 XXX-XXXX

Steps: 7 Select the Curriculum and click "Complete Registration". The **Finalize Registration** button will appear then clickthe button to enter the course introduction page. Select the "View Courses" button at "Mahidol University" to access the main page.

Select Curriculum

* indicates a required field.

You will be provided a series of enrollment questions. Your responses will determine the curriculum for the courses you are going to take. Please read the questions carefully. Please read the responses carefully to make the best choice.

Question 1

Human Subjects Research

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

Choose one answer

- ○ Biomedical Researchers
- ○ Social & Behavioral & Humanities Researchers
- ○ CRC & CRA
- ○ IRB Staff Biomedical Panel
- ○ IRB Staff Social, Behavioral & Humanity Panel
- ○ Student Biomedical Research
- ○ Student Social, Behavioral & Humanity Research
- ○ IRB Biomedical Panel
- ○ IRB Social, Behavioral & Humanity Panel
- ○ Not at this time.

Figure 9

How to Log In

1. Use Web Browser such as Internet Explorer, Google Chrome, Mozilla Firefox Type

   https://www.citiprogram.org/ at URL and Enter. You will see this page, then select "Log In"
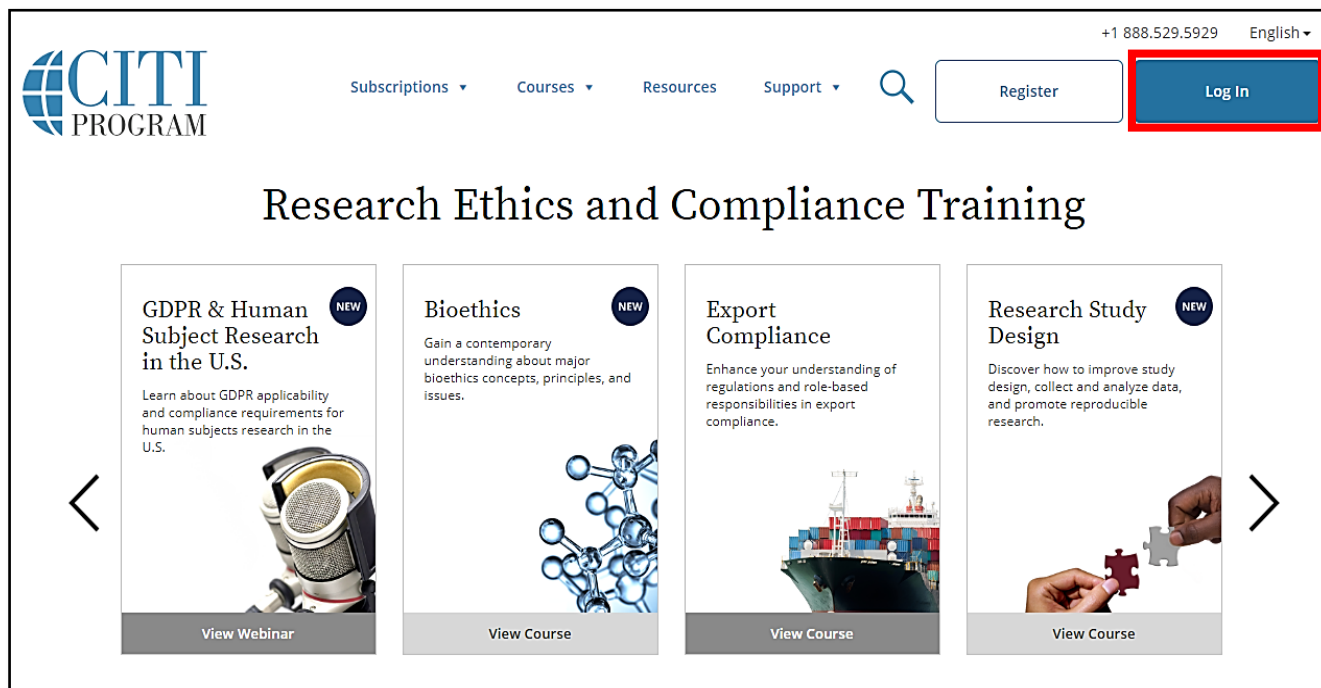
Figure 10

2. Type User Name and Password and click "Log In".

Figure 11

Receiving User Name or Password through your E-Mail

1. Request the system to send the User Name or Password via E-Mail.

If you forget the User Name or Password, click Link: "Forgot?" at the side of the text box

Figure 12

In the case of forgetting the User Name, enter the E-Mail that corresponds to the first application and click "Send My Username". The Link Delivery System will send the username and password to your E-Mail.
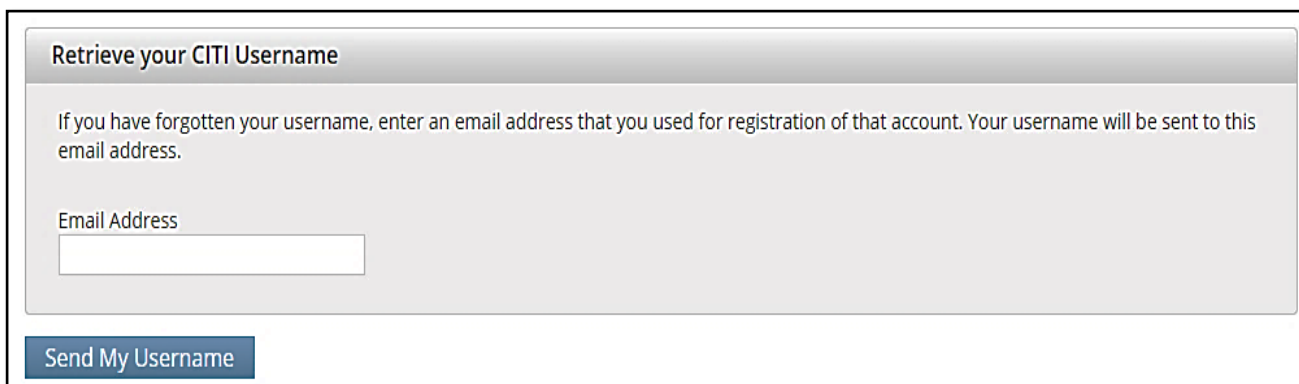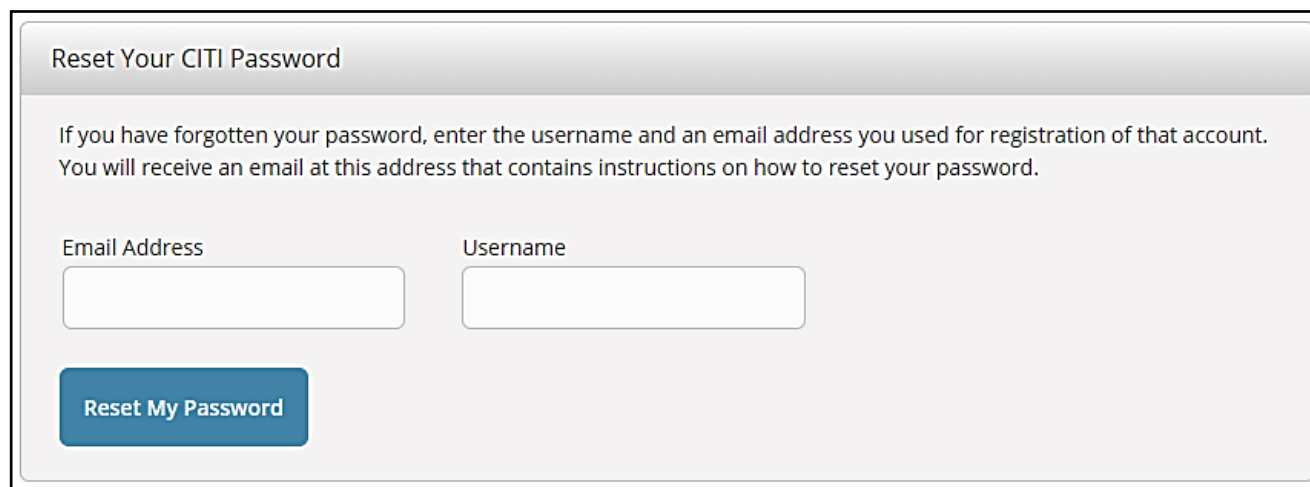
Figure 13

In the case of forgetting the password, enter the E-Mail and Username that corresponds to the first application and click "Reset My Password". The Link Delivery System will send the password to your E-Mail.
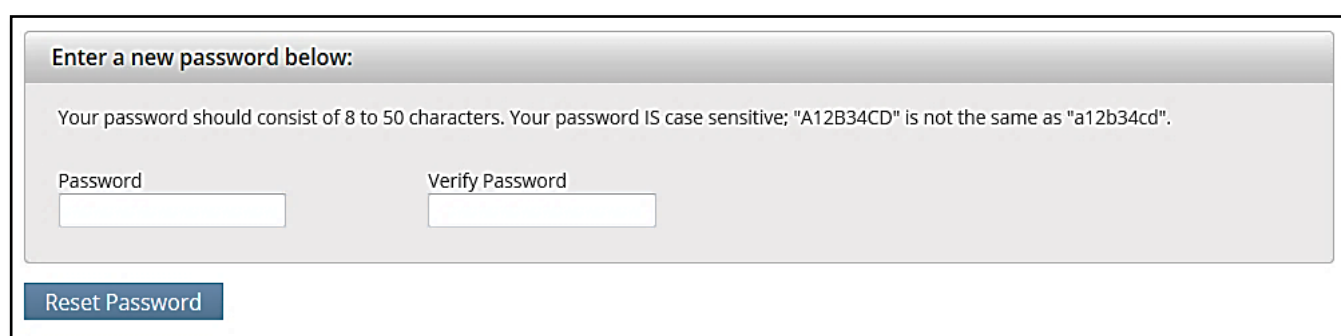
Figure 14

2. Set the new password

When the system send a link to set a new password to your E-Mail as requested in Section 1.3. Click on Link. The window will show the image below. Enter the new password and confirm the new password (Verify Password) then click "Reset Password"

Figure 15

CITI Program Introduction

1. Main Menu of CITI Program

About the course	Store a list of courses that have been studied	Search for information within the website	Change language

Continuing Education Unit (CEU)	Help Center for using the program	Show account details
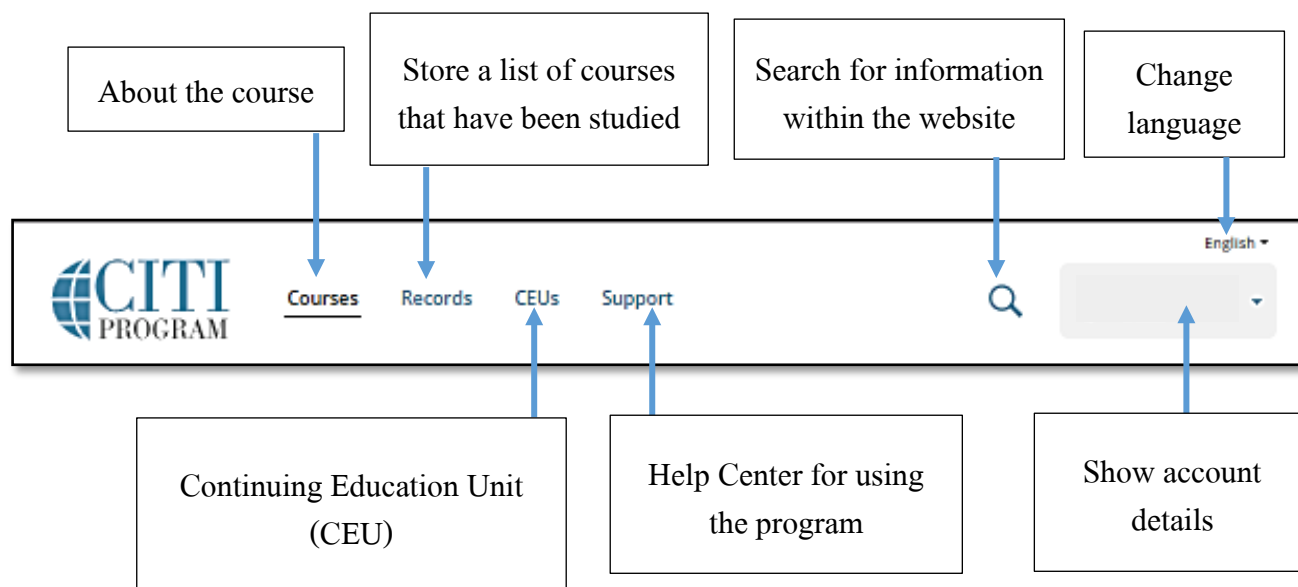
Figure 16

2. Show CITI Program usage information

- Courses Completed: Show the number of courses passed

- Day of Membership: Displays the number of days that are members of the program.

- Add Institutional Affiliation: Add recommendations from other affiliated institutions

- Register as Independent Learner: Register as an independent learner. (Use the program to choose various courses Freely and with registration fees)

Figure 17

3. **Course introduction**

Figure 18

4. **Register as Independent Learner**: You can access through institutional affiliation as MU member but if you want to access to any course out of MU subscription, you need to purchase that course by your own expense.

Figure 19

Courses for Mahidol University

- **The first page of the course for Mahidol University** shows information about your learning. If you want to begin click "start now".

Figure 20

- **Learner Tools for Mahidol University** to consist of

  - Add a Course : Add new courses (See more details in the topic: Add another module)

  - Remove a Course

> Removing a course will un-enroll you from the group. When you are un-enrolled from the group you will not receive expiration notices and will not be automatically enrolled in the next stage when the current stage expires.

The courses in which you are currently enrolled at *Mahidol University* are listed below. Your most recent record is shown for each course. Select the course(s) you want to remove from your curriculum and then use the Submit button at the bottom of this page. You will be asked to confirm your choice(s) on the next page.

Remove	Course	Stage	Completion Report	Completion Date	Expiration Date
☐	Social & Behavioral & Humanities Researchers	Basic Stage	29955985	**Due Now**	-

Cancel   Submit

Figure 21

- View Previously Completed Coursework

Mahidol University Records (ID 3532)

Human Subjects Research - Social & Behavioral & Humanities Researchers (ID 116940)

Stage	Record ID	Passing Score	Your Score	Start Date	Completion Date	Expiration Date	Gradebook	Completion Record
Basic Stage	29955985	-	-	Due Now	-	-	View	-

Figure 22

- Update Institution Profile

- Remove Affiliation

Figure 22

Courses Ready to Begin

1. Once the member has successfully logged in, click **"View Courses"** on Institutional Courses for Mahidol University.

Figure 24

2. Scroll the scrollbar down to box "Courses Ready to Begin". You will find the name of the course selected, then click "Start Now".
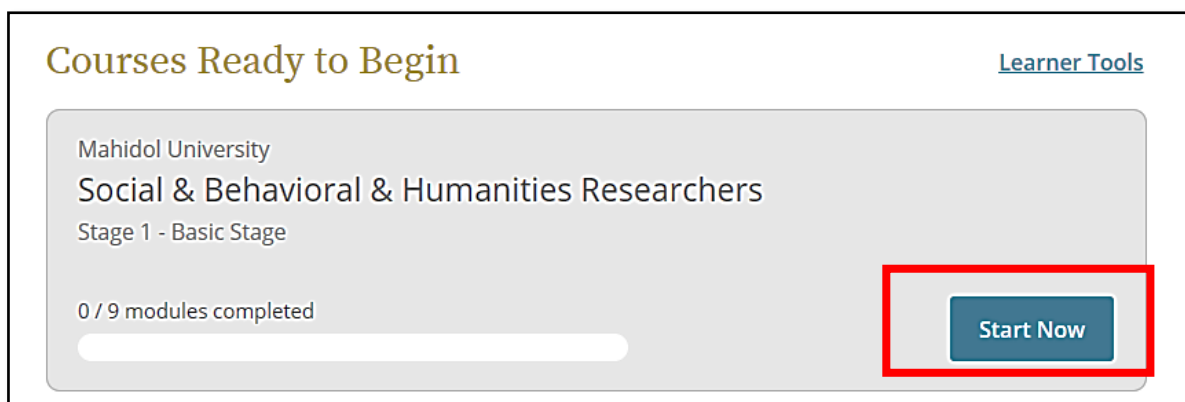

Figure 25

3. On the page showing the course rules for learning. Click the box labeled "I AGREE to the above, the Terms of Service, and the Privacy and Cookie Policy, in order to access CITI Program materials." Then click "Submit".
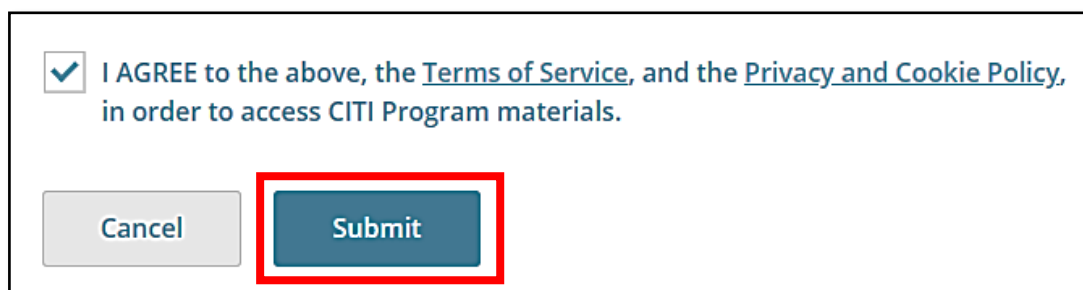
Figure 26

4. In each course, the instructions will show the number of required modules that you have to complete, the number of elective modules that you can choose to study as you like and the average score as a minimum passing level. If you complete all the requirement, the certificate of completion will be issued.
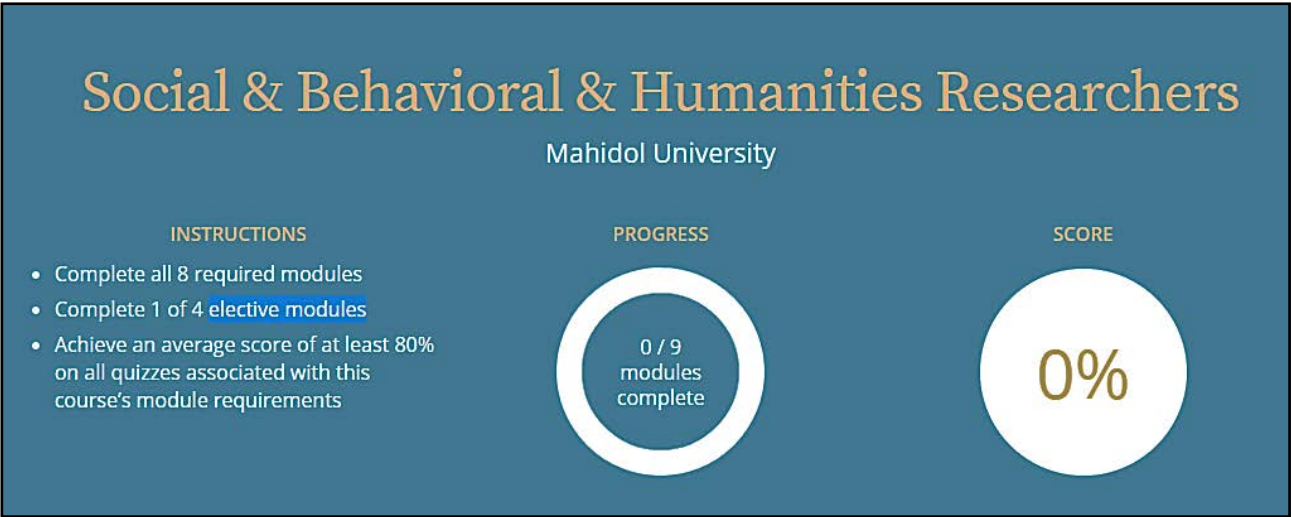
Figure 27

In each course, there will be Supplemental Modules displayed for members who want to study additional courses related. In this part, you can't choose to learn more.

5. You can choose to study any module, either required or elective modules, as you like by click "Start" at that topic.

Figure 28

Take the quiz

1. After complete reading the article, then click "Take the Quiz" at the end of the article.
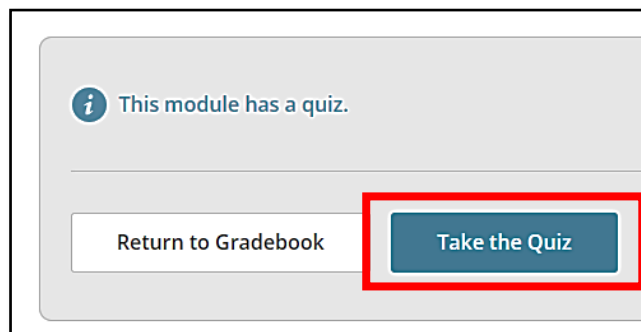
Figure 29

2. The program will have instructions to do the exam. After answering all questions, click "Submit" to send the answer.

3. The program will evaluate, shows the correct answer and your score.

- You may choose "Return to Gradebook" if you satisfy with your score

- If you want to continue your study, click "View the next required Module"

- If you want to learn more to increase understanding in the same module, click "Review Module/Retake Quiz"

- You can feedback by click "Leave feedback for this Module"

- You can go back to see the curriculum by click "View Courses"
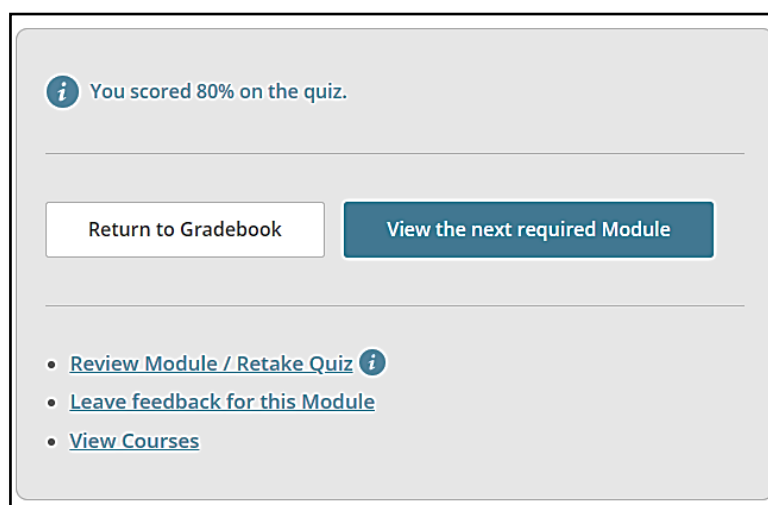
Figure 30

4. After complete all module with minimum require score, the program will show "Congratulations! You have completed this Course.", then click "View Post-Course Completion Options".
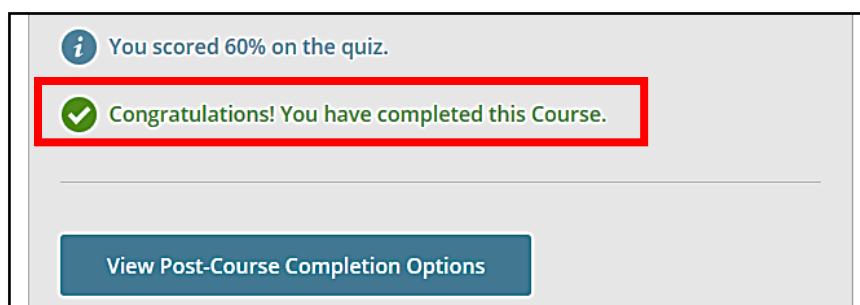
Figure 31

Access your Completion Records: Print or share the Link Certificate of course training
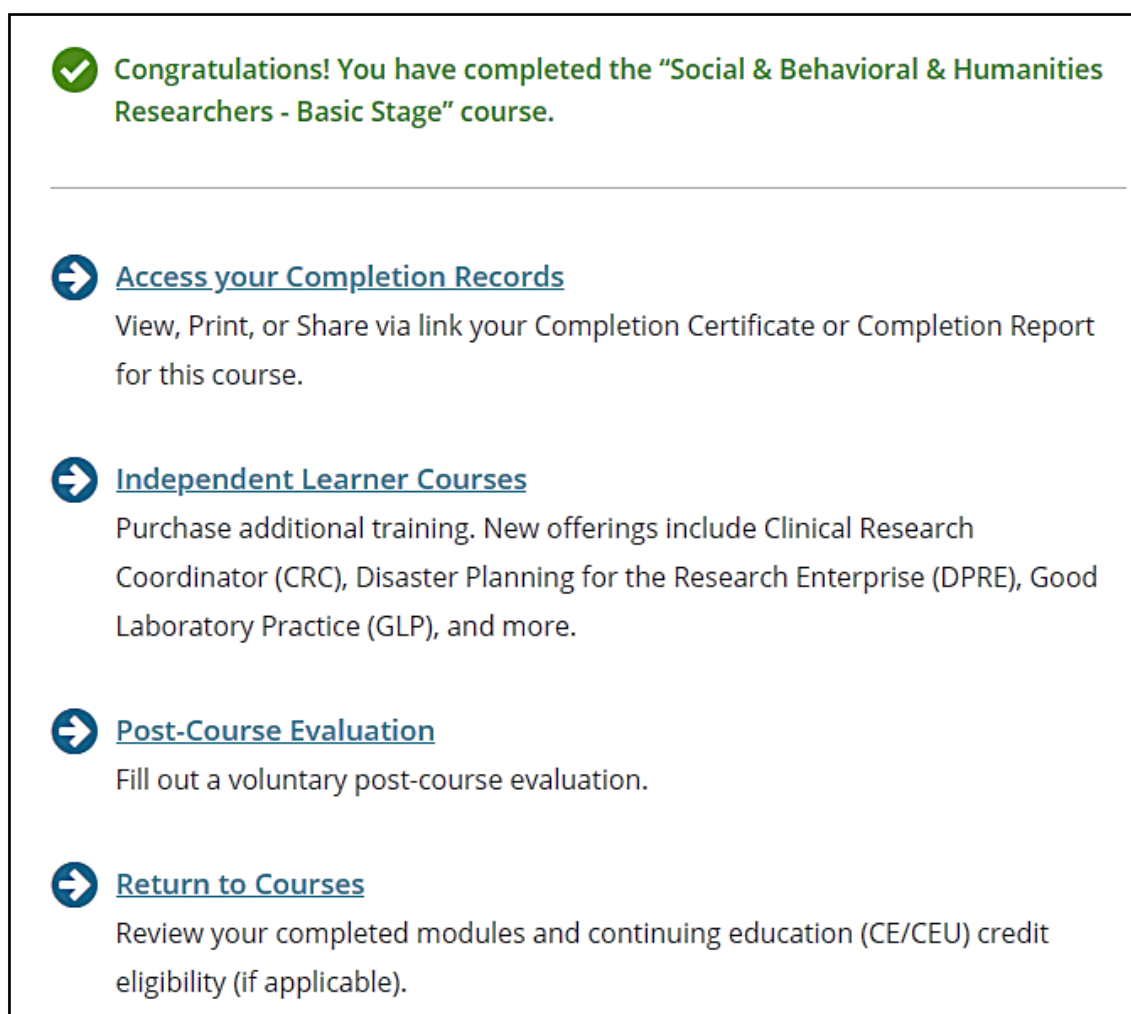
Figure 32

Print Certification

1. Click "Access your Completion Records"

- Access your Completion Records

   → **Access your Completion Records**
   View, Print, or Share via link your Completion Certificate or Completion Report
   for this course.

Figure 33

- There are 2 types of display: Completion Report and Completion Certificate. To view or print, click "View / Print" or "Copy Link" as needed.

Mahidol University
ID 3292

Social & Behavioral & Humanities Researchers

Name	Stage	Completion Date	Expiration Date	Record ID
sirivimol nakthong	1 - Basic Stage	09-Jan-2019	08-Jan-2023	29955985

Completion Report

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.

View / Print   Copy Link ⧉

Completion Certificate

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.

View / Print   Copy Link ⧉

Figure 34

2. If you want a new copy of the Certificate of Completion, enter the program and select Top Menu >> Record, you will find the record as sample below and can view/print or share the certificate by click under the column "Completion Record".

Figure 35

3. The certificate has 2 pages. The first page shows personal data, score and the date of completion. The second page shows supplemental modules that you have learnt. (Explanation about CITI (Collaborative Institutional Training Initiative) Transcript detail)

Figure 36

4. The certificate will contain the information as shown below.

Figure 37

Log Out

The upper left corner of the screen Select the arrow head beside the account information and click the Log Out button.
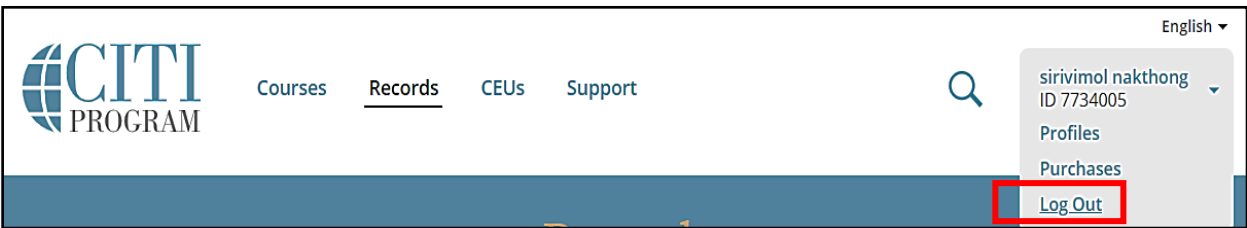

Figure 38

Add another module

1. Enter the program. Choose View Courses for Mahidol University Courses.

2. Add a Course in Learner Tools for Mahidol University

3. Choose Courses

Option 1: Human Subjects Research

Learner Group	Qualifications of trainees
Biomedical Researchers	Researchers who conduct biomedical research
Social & Behavioral & Humanities Researchers	Researchers who conduct social science research
CRC & CRA	Clinical Research Center staff or Contract Research Assistants *
IRB Staff - Biomedical Panel	IRB staff who handle mainly biomedical research protocols
IRB Staff - Social, Behavioral & Humanity Panel	IRB staff who handle mainly social science research protocols
Student Biomedical Research	Students who participate in biomedical research team
Student Social, Behavioral & Humanity Research	Students who participate in social science research team
IRB Biomedical Panel	Board Member of IRB who review mainly biomedical research protocols
IRB Social, Behavioral & Humanity Panel	Board Member of IRB who review mainly social science research protocols
Not at this time.	-

* Clinical research means research related to medical treatment and health promotion, which includes research for diagnosis, treatment, health rehabilitation after illness and disease prevention; which may require medication use, medical tools or other treatment methods such as surgery, physical therapy or other alternative treatments.

Option 2: Good Clinical Practice (GCP)

Learner Group)	Qualifications of trainees
Researcher - Drug	Researchers who conduct clinical research using investigational drugs
Researcher - Biological	Researchers who conduct clinical research using biologic product
Researcher - Device	Researchers who conduct clinical research using medical tools
CRC & CRA	Clinical Research Center staff or Contract Research Assistants
Monitor, IRB Member	IRB Board Member
Auditor, IRB Chair	IRB Chair
Not at this time.	-

Option 3: Information Privacy Security (IPS)

Learner Group	Qualifications of trainees
IPS for Clinicians	Clinicians, para-medical personnel
IPS for Researchers	Researchers
IPS for Students and Instructors	Students and Instructors
IPS for Fund raisers	Fund raisers
IPS for Marketers	Marketers
I am not required to complete the IPS course at this time.	-

Question 4: Responsible Conduct of Research

Learner Group	Qualifications of trainees
Biomedical Responsible Conduct of Research Course	Biomedical researchers
Social and Behavioral Responsible Conduct of Research Course	Social science researchers
Physical Science Responsible Conduct of Research Course	Physical science researchers
Humanities Responsible Conduct of Research Course	Humanities researchers
Responsible Conduct of Research for Engineers	Engineering researchers
Responsible Conduct of Research for Administrators	Institutional administrators
Not at this time.	-

Option 5: Laboratory Animal Research (For researchers who need to use experimental animals in research)

4. Press the Submit button to return to the main page. With the selected topics appearing in the Course column