

CITI Online Training Program

Biomedical Research Course

Pornpimon Adams ORS, Faculty of Tropical Medicine Mahidol University

Wisdom of the Land



CITI Program

- CITI is the **C**ollaborative Institutional **T**raining Initiative.
- โปรแกรมการศึกษาและฝึกอบรมจริยธรรมการวิจัย ด้วยตนเองแบบ
 Online ที่มหาวิทยาลัยมหิดล เช่าลิขสิทธิ์จาก University of Miami
 ดังนั้นบุคลากรและนักศึกษาของมหิดลจึงใช้ได้ฟรี
- Course ที่สามารถเลือกศึกษาและฝึกอบรมได้มี 6 Courses
 - Human Subject Research (HSR) Series
 - Good Clinical Practice (GCP)
 - Animal Care and Use (ACU
 - Information Privacy and Security (IPS)
 - Responsible Conduct of Research (RCR)



วัตถุประสงค์

- เรียนรู้ขั้นตอนการลงทะเบียนใช้งาน CITI Program
- การเลือก Course ที่จะอบรมให้เหมาะสม



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CE Certified Courses

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Introducing the Fundamentals of





ให้พิมพ์'Mahidol' ในช่องจะปรากฏชื่อ Mahidol University ขึ้นมาให้กดเลือก

CITI - Learner Registration
Steps: 1 2 3 4 5 6 7
You must make a selection below.
Select Your Organization Affiliation
Search for organization: Enter full or partial name 🥹
Mahidol University
Can't find your institution? It may use Single Sign On. Check here.
To find your organization, enter its name in the box above, then pick from the list of choices provided. If the selection is correct, click the "Continue to Step 2" button immediately below. To clear your selection and try again, click the "Search Again" button.
I AGREE to the Terms of Service for accessing CITI Program materials.

ให้ tick 'I AGREE' และ click 'Continue to Step 2'.



ควรใช้'@mahidol' email address.

* Email Address * Verify email address We urge you to provide a second email address, if you have one, in case messages are blocked or you lose the access the first one. If you forget your username or password, you can recover that information using either eaddress.	* First Name	* Last Name
We urge you to provide a second email address, if you have one, in case messages are blocked or you lose the access the first one. If you forget your username or password, you can recover that information using either eaddress.	* Email Address	* Verify email address
	We urge you to provide a secon	l email address, if you have one, in case messages are blocked or you lo
Secondary email address Verify secondary email address	We urge you to provide a secon access the first one. If you forge address.	l email address, if you have one, in case messages are blocked or you lo your username or password, you can recover that information using ei

และสามารถเพิ่ม back up email (เช่น Gmail). Click to continue.

Mahidol University Faculty of Tropical Medicine Step 5 – สร้าง username and password

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

ระบบจะให้ใส่คำถาม security question เมื่อใส่คำตอบที่ security answer เสร็จแล้ว ให้ Click to continue.



ให้พิมพ์ 'Thailand' ในช่องจะปรากฏชื่อ Thailand ขึ้นมา ให้กดเลือก

	* 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.	
	Thailand	
	Continue To Step 5	
Cli	ck to continue.	



Step 7 – ตอบคำถามว่าจะเรียนเพื่อรับเครดิต หรือไม่

* 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





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.

No

Click 'No'.



It's your choice on how you answer these two questions

O Yes	
◎ No	
Not sure. Ask me later	

* Can CITI Program contact you at a later date with marketing information? 🥹	
◎ Yes	
[©] No	

Continue To Step 6

Click to continue.





Please provide the following information requested by Mahidol University
* indicates a required field.
Language Preference
* Institutional Email Address
Gender
Highest Degree
Employee Number
* Department
* Role In Research
Principal Investigator *



Role in research options

- Clinical Researcher
- Co-Investigator
- Compliance Officer
- Data Manager
- IACUC Administrator
- IACUC Chair
- IACUC Member
- Institutional Official
- Interviewer
- IRB Administrator
- IRB Chair
- IRB Member
- Lab. Research Staff

- Pharmacist
- Recruiter
- Research Administrator
- Research Assistant
- Research Fellow-Post Graduate
- Research Integrity Officer
- Site coordinator
- Social worker
- Statistician
- Student Researcher- Graduate Level
- Student Researcher- Undergraduate
- Study Coordinator
- Study Nurse
- Veterinarian



เลือก 'Biomedical Researchers'.



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.





ขณะนี้ยังไม่ต้องเลือกเรียน GCP course. Choose 'Not at this time'





ขณะนี้ยังไม่ต้องเลือกเรียน IPS course. Choose 'I'm not required…'

Question 3

Information Privacy Security

Please make the appropriate selection if you are required to complete the Information Privacy Security (IPS) course.

Choose one answer

- IPS for Clinicians
- IPS for Researchers
- IPS for Students and Instructors
- IPS for Fundraisers
- IPS for Marketers
- I am not required to complete the IPS course at this time.







ขณะนี้ยังไม่ต้องเลือกเรียน RCR course Choose 'Not at this time'

Question 4

Responsible Conduct of Research

Please make your selection below to receive the courses in the Responsible Conduct of Research.

Choose one answer

- Biomedical Responsible Conduct of Research Course
- Social and Behavioral Responsible Conduct of Research Course
- Physical Science Responsible Conduct of Research Course
- Humanities Responsible Conduct of Research Course
- Responsible Conduct of Research for Engineers
- Responsible Conduct of Research for Administrators
- Not at this time.







If you will use animals in your research, select the type of work and species. If you won't use animals, just click 'Complete Registration'.

Question 5

Laboratory Animal Research

Do you conduct studies that use Lab animals?

1. If YES, then you must complete the Basic course and the appropriate species specific modules.

2. If you are an IACUC Member you should complete the "Essentials for IACUC Members".

3. Choose the appropriate species specific electives according to your research interests.

Choose all that apply

- "Working with the IACUC Course" is required if you plan to use lab animals in your work.
- If you are an IACUC Member you are required to complete the "Essentials for IACUC Members" course now.
- IACUC Community Member
- Institutional Officials
- 🗆 IACUC Chair
- Post-Approval Monitoring (PAM)

If you plan to conduct studies that have the potential to cause "more than momentary pain and distress" in Mice or Rats you should complete the module on "Minimizing Pain and Distress".

Choose the appropriate species specific electives depending on your work or interests.

- I work with Frogs, Toads or other Amphibians
- I work with Mice. Family: Muridae Cricetidae
- I work with Rats. Genus: Rattus



Click to finalize

CITI - Learner Registration

Welcome to the CITI Program. Your registration with Mahidol University is complete.

Finalize Registration







ทำ bookmark หน้านี่ไว้. Click 'Biomedical Researchers' to start



Main Menu / My Courses

You are now enrolled in the course(s) you selected.

✓ Mahidol University Courses		
Course 🕜	Status 🕜	Completion Record 📀
Biomedical Researchers Not Started Not Earned		Not Earned
My Learner Tools for Mahidol University		
Add a Course		
Remove a Course		
View Previously Completed Coursework		
② Update Institution Profile		
Demous Affiliation		



หลังจากเลือก course แล้ว ต้องอ่านกติกาให้ละเอียด เช่น course Biomedical researchers กำหนดให้เรียน 6 บทเรียนบังคับ และ 3 บทเรียน ต้องเลือก และต้องสอบได้ 80% จึงผ่าน



Biomedical Researchers - Basic Stage

To pass this course you must:

- · Complete all 6 required modules
- Complete 3 of 8 elective modules
- · Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or the overall score

You have unfinished required or elective modules remaining

Complete The Integrity Assurance Statement before beginning the course

Your Current Score

0%

Mahidol University Faculty of Tropical Medicine Step 13 – ข้อสัญญาและข้อตกลงในการทำ แบบทดสอบ (1)

Biomedical Researchers - Basic Stage

To pass this course you must:

- · Complete all 6 required modules
- · Complete 3 of 8 elective modules
- · Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or the overall score

You have unfinished required or elective modules remaining

Complete The Integrity Assurance Statement before beginning the course

Required Modules		
	Date Completed	Score
Informed Consent (ID: 3)	Incomplete	0/0 (0%)
Research Involving Children (ID: 9)	Incomplete	0/0 (0%)
History and Ethics of Human Subjects Research (ID: 498)	Incomplete	0/0 (0%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	Incomplete	0/0 (0%)





aculty of Tropical Medicine Step 13 – ข้อสัญญาและข้อตกลงในการทำ แบบทดสอบ(2)

Click 'Agree' and 'Submit'.

Assurance Statement				
Ailada Angatchariya:				
CITI Program Terms of Service include the following provisions. Please read them carefully.				
No Account Sharing:	I will not share my username and password with anyone. I will contact the CITI Program Help Desk if I believe my account has been compromised.			
Do My Own Work:	I will complete all required quizzes and any other assessments by myself, using only my own work.			
No Quiz Sharing:	I will not share CITI Program quiz questions or answers on any website, via email, photocopying, or any other means.			
No Cheating:	I will not engage in any activities that would dishonestly improve my results, or improve or hurt the results of other learners.			
My Actions Are Logged:	I understand that CITI Program keeps account activity logs, including computer IP addresses, time spent in each content area, number of quiz attempts and scores. Allegations of inappropriate use will be investigated, and the results reported to my institution.			

Check the box to accept, then click the Submit button:

I AGREE to the above and the other Terms of Service for accessing CITI Program materials.



Submit



	Required Modules			
		Date Completed	Score	
_/	Informed Consent (ID: 3)	Incomplete	0/0 (0%)	
	Research Involving Children (ID: 9)	Incomplete	0/0 (0%)	
	History and Ethics of Human Subjects Research (ID: 498)	Incomplete	0/0 (0%)	
	Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	Incomplete	0/0 (0%)	
	Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	Incomplete	0/0 (0%)	
	Conflicts of Interest in Human Subjects Research (ID: 17464)	Incomplete	0/0 (0%)	
	Elective Modules			
		Date Completed	Score	
		2010 Completed	22010	

Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)

Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)

Incomplete (0%)

Incomplete

0/0



The first step is to read all the information. Make notes of key facts and concepts. Use a dictionary for any words you don't understand.

Introduction

It is important to understand that informed consent is a process that begins with the recruitment and screening of a subject and the signing of the consent document, and continues throughout the subject's involvement in the research and beyond study termination. It includes:

- Recruitment efforts encompassing the means of first creating awareness or contact and spanning everything from medical record review to advertisements and other recruitment materials.
- Providing specific information and answering questions about the study to subjects in a way that is understandable to them while giving subjects adequate time to consider participation.
- Obtaining the voluntary agreement of subjects to take part in the study. While the subject may agree to participate in the study, subjects may withdraw at any time. Part of the ongoing nature of the consent process is verifying the subject's continued interest in participating in the study.
- Making plans for the provision of new information to be shared with former subjects, even after the study ends.

There is consensus among researchers and Institutional Review Board (IRB) reviewers regarding the importance of informed consent. Informed consent is a demonstration of how researchers and those involved in human subjects research show respect to research subjects, and it is mandated by the U.S. Department of Health and Human Services (HHS) at 45 CFR 46 and the U.S. Food and Drug Administration (FDA) at 21 CFR 50. These regulations were developed to:

- Protect human subjects.
- Ensure that potential study subjects clearly understand the benefits and risks associated with their participation in a study.
- Provide the potential study subjects with all information needed to reach a decision on whether or not to participate in a research study.

This module provides a basic understanding of informed consent and the process of obtaining informed consent.



Open any Case Studies. They are a good way to learn more about the practical applications of what you are learning.



A researcher proposes a randomized trial of an investigational drug in patients about to undergo surgery for acute appendicitis. The investigational drug (or placebo, depending on which arm the subject is assigned to) is administered immediately prior to the surgery. If the investigational drug works, it will mean less pain and maybe less need for other pain medicines like morphine. The researcher who is also the surgeon performing the operation, proposes to have a nurse explain the research in the "pre-op" area. The nurse will explain the research while the patient is being prepared for the operation and having an IV started, as well as blood pressure and other measurements taken. The surgeon will then arrive, get consent for the operation, and get the patient's signature on the research consent form. If the patient does not speak English, an interpreter will answer the patient's questions. The patient will sign the English language consent form.

Is the proposed consent process appropriate for this situation?

Close Case Study



After reading and understanding the information in the module, you need to take the quiz. The link is at the very end of the page.

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Klimaszewski, Angela D., S. Anderson, and M. Good edited by Angela D. Klimaszewski and Jennifer L. Aikir National Cancer Institute (NCI). 2016. "Clinical Trials I U.S. Department of Health and Human Services "Frequently Asked Questions About Human Researc U.S. Food and Drug Administration (FDA). 2012. "G Boards: Questions and Answers on Informed Conse Accessed March 15, 2016. U.S. Food and Drug Administration (FDA). 2014. "Infc Clinical Investigators, and Sponsors." Last updated N Original Release: July 2003 Last Updated: July 2017 Take the guiz for Informed Consent Return to the module list for this course

Accessibility Copyright Privacy I



There are between 5 and 10 multiple choice questions. Make sure to read the questions and possible answers carefully.

Question 1
Multiple Choice/Single Answer - Select only one answer
The purpose of informed consent is:
 To provide a potential subject with appropriate information in an appropriate manner and allow that person to make an informed decision about participation in research.
To document the investigator's participation in the consent process.
To obtain a signature from a study subject in order to protect the investigator, the study staff and the institution.
To obtain a signature from a study subject in order to document his or her agreement to participate in research.
Question 2

Multiple Choice/Single Answer - Select only one answer

A 46-year-old man is currently enrolled in a Phase 2 study of a drug for severe diabetic neuropathy. While the



After clicking submit you will instantly get your results. Even if you got 100% make sure you read the 'comments' for any extra explanation or information.

Quiz Results - Informed Consent

You correctly answered 5 of 5 and received 5 of 5 possible points.

Scroll down to review the quiz questions and the explanation of the answers.

Question 1

Question The purpose of informed consent is:

Your Answer To provide a potential subject with appropriate information in an appropriate manner and allow that person to make an informed decision about participation in research.

Correct Answer To provide a potential subject with appropriate information in an appropriate manner and allow that person to make an informed decision about participation in research.

Comment The purpose of the Informed Consent process is to ensure human research subjects are provided all of the information necessary to make informed choices about participating in research.



If you didn't get at least 80%, you will need to retake the module. The link for this is at the end of the results page.

Your Answer	In the event of any injury you may have related to this research, you will be given medical treatment.
Correct Answer	l waive any possibility of compensation for injuries that l may receive as a result of participation in this research.
Comment	Exculpatory language is written content in the consent document through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Such language is specifically prohibited.
Points Earned	0



Take the next required module → Research Involving Children Return to the module list for this course View this module again and re-take the quiz. Note: You can re-take quizzes until your Completion Report is issued. Submit a comment about this exam

Go to the Main Menu



When you have competed all the requirements of the course, you will receive a completion report. You must print this and submit it with your protocol.

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

* NOTE: Scores on this <u>Requirements Report</u> reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

Name: Institution Affiliation: Institution Email: Institution Unit:	Nicola Ball (ID: 6447205) Mahidol University (ID: 3292) nicola.bal@mahidol.ac.th Faculty of Tropical Medicine		
Curriculum Group: Course Learner Group: Stage:	Responsible Conduct of Res Same as Curriculum Group Stage 1 - RCR	earch for Administrators	
Record ID: Completion Date: Expiration Date: Minimum Passing: Reported Score*:	23835879 22-Aug-2017 21-Aug-2020 80 100	Example only	
REQUIRED AND ELECTIVE MO	DULES ONLY	DATE COMPLETED	SCORE
Collaborative Research (RCR-Ba Conflicts of Interest (RCR-Basic) Data Management (RCR-Basic) (inancial Responsibility (RCR-Ba Mentoring (RCR-Basic) (ID: 1660 Research Misconduct (RCR-Basic)	sic) (ID: 16598) (ID: 16599) ID: 16600) sic) (ID: 16601) 2) c) (ID: 16604)	11-Jul-2017 17-Jul-2017 18-Jul-2017 21-Aug-2017 21-Aug-2017 22-Aug-2017	5/5 (100%) 5/5 (100%) 5/5 (100%) 5/5 (100%) 5/5 (100%) 5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?ke0795292-1911-46e9-872a-d77f673dc46a-23835879

Collaborative Institutional Training Initiative (CITI Program) Email: <u>support@citiprogram.org</u> Phone: 885-529-5929 Web: <u>https://www.citiprogram.org</u>



Other online courses and resources – other CITI courses

Once you are enrolled with CITI you also have access to other courses.

One good one to complete is 'Responsible Conduct of Research'. As with the other course, you will receive a certificate of completion.

Responsible Conduct of Research

Please make your selection below to receive the courses in the Responsible Conduct of Research.

Choose one answer

- Biomedical Responsible Conduct of Research Course
- Social and Behavioral Responsible Conduct of Research Course
- Physical Science Responsible Conduct of Research Course
- Humanities Responsible Conduct of Research Course
- Responsible Conduct of Research for Engineers
- Responsible Conduct of Research for Administrators
- Not at this time.



Other online courses and resources – The Lab

https://ori.hhs.gov/thelab

This is an interactive movie where you can play different characters. It's an engaging way to learn more about how to deal with research misconduct.





Other online courses and resources – fhi360

https://www.fhi360.org/sites/all//libraries/webpages/fhiretc2/index.html

This course is available in different formats – if needed you can download it and complete it offline.





Other online courses and resources – ORI links

https://ori.hhs.gov/human-subject-research-0

This page brings together selected resources. There is a mixture of online units, videos and documents.

Human Subject Research

Web Module	Bryn Mawr College and the Massachusetts College of Pharmacy and Health Sciences Ethics and Research in the Community
Zip	University of California Los Angeles Teaching the Responsible Conduct of Research in Humans
Related Resources	U.S. Office for Human Research Protections Multimedia Mini Tutorials & Collection of Videos and Webinars &
Related Organizations	



Other online courses and resources – NIH

https://phrp.nihtraining.com/

This is designed for researchers with or applying for NIH funding, but much of it is relevant for everyone.





Thank you for listening

Any questions?