Mahidol University
Faculty of Tropical Medicine

CITI Online Training Program

Biomedical Research Course

Pornpimon Adams
ORS, Faculty of Tropical Medicine
Mahidol University

Wisdom of the Land

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Faculty of Tropical Medicine

CITI Program

- CITI is the **C**ollaborative **I**nstitutional **T**raining **I**nitiative.
- 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)

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วัตถุประสงค์

- เรียนรู้ขั้นตอนการลงทะเบียนใช้งาน CITI Program
- การเลือก Course ที่จะอบรมให้เหมาะสม

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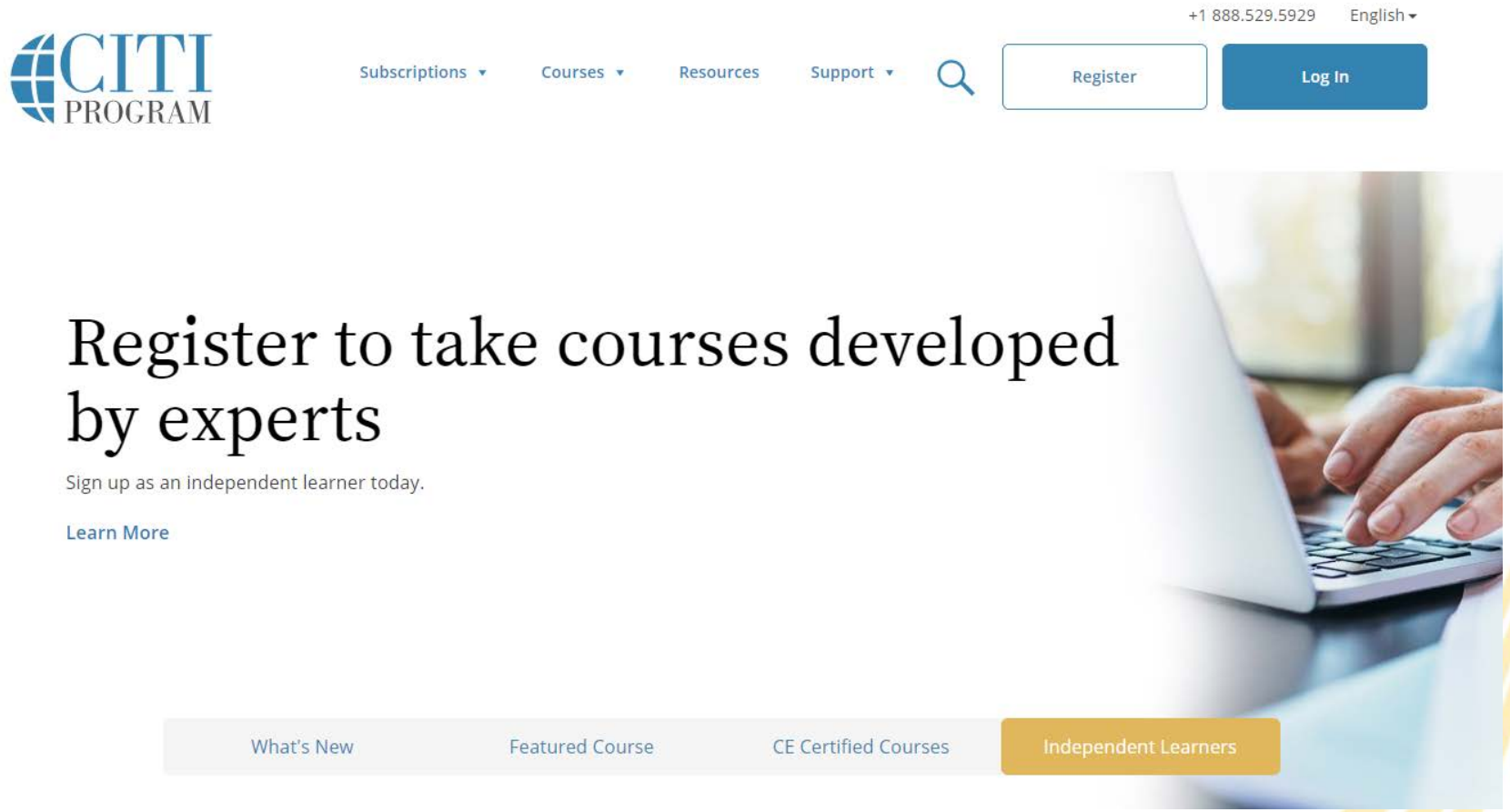
Step 1 – เข้า website

Go to www.citiprogram.org.



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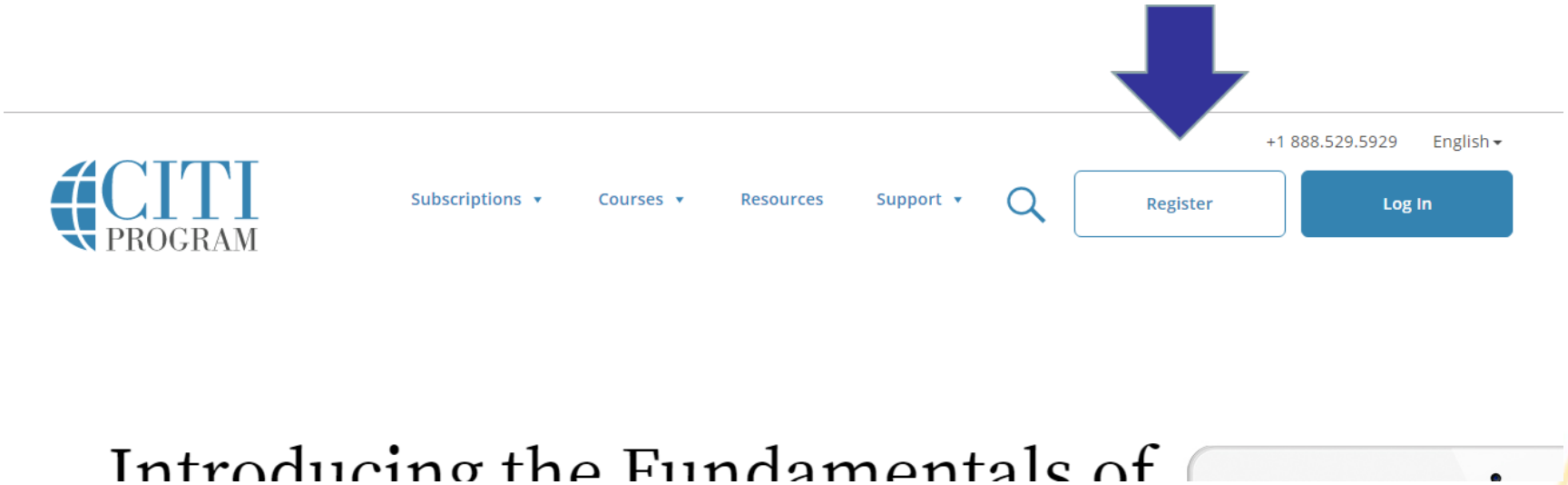
Step 2 – click Register



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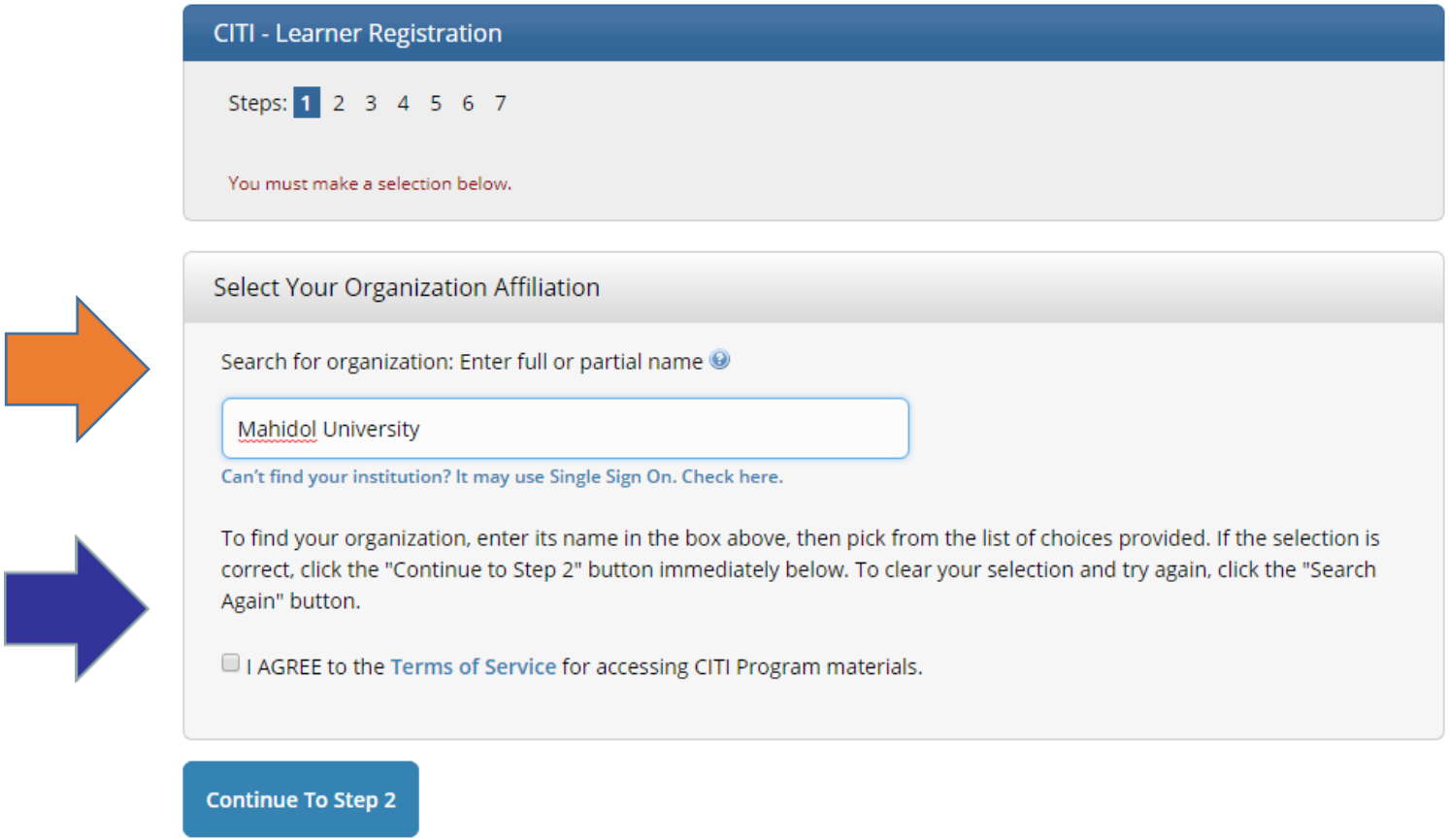
Step 3 - Select your Organization Affiliation

ให้พิมพ์‘Mahidol’ ในช่องจะปรากฏชื่อ Mahidol University ขึ้นมาให้กดเลือก



ให้ tick ‘I AGREE’ และ click ‘Continue to Step 2’.

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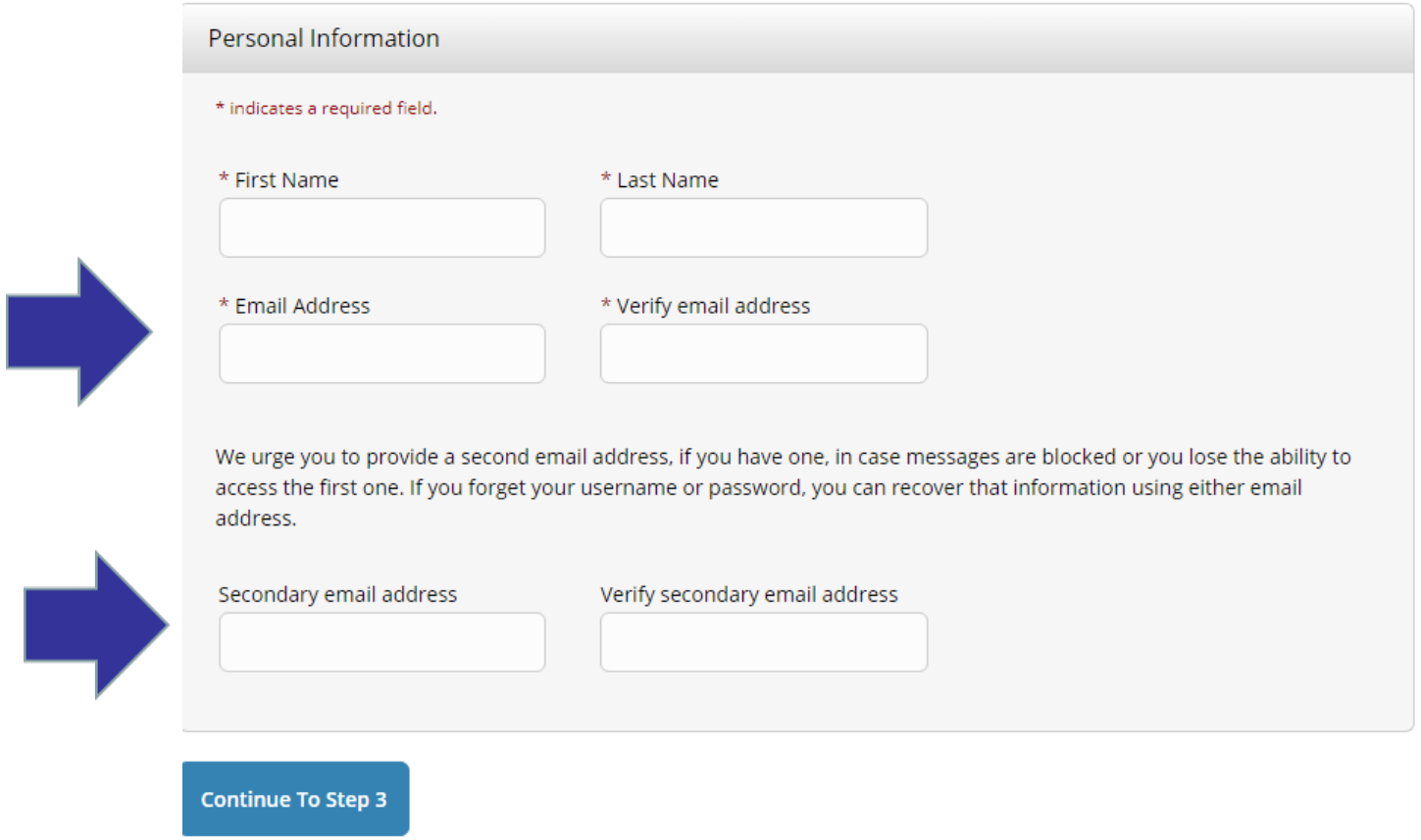
Step 4 – ใส่ข้อมูล Personal Information

ควรใช้‘@mahidol’ email address.



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

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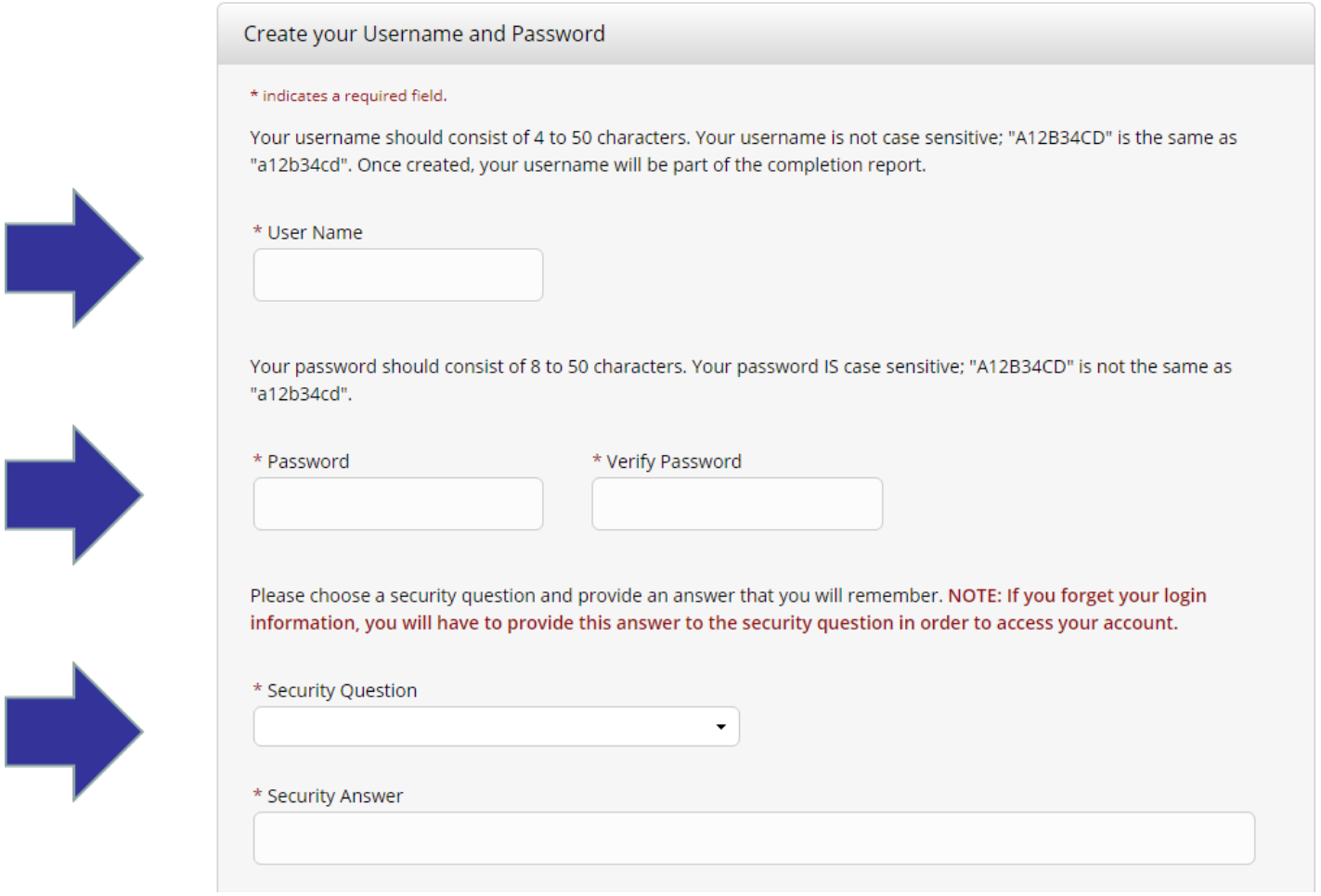
Step 5 – สร้าง username and password



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

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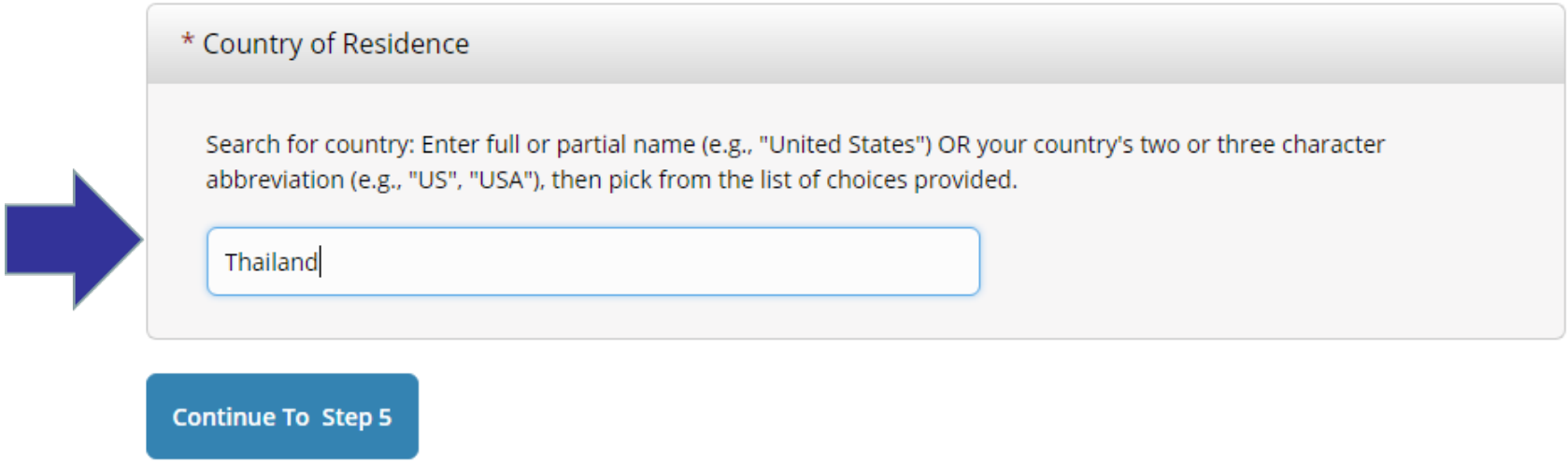
Step 6 – Country of Resident

ให้พิมพ์ ‘Thailand’ ในช่องจะปรากฏชื่อ Thailand ขึ้นมา ให้กดเลือก



Click to continue.

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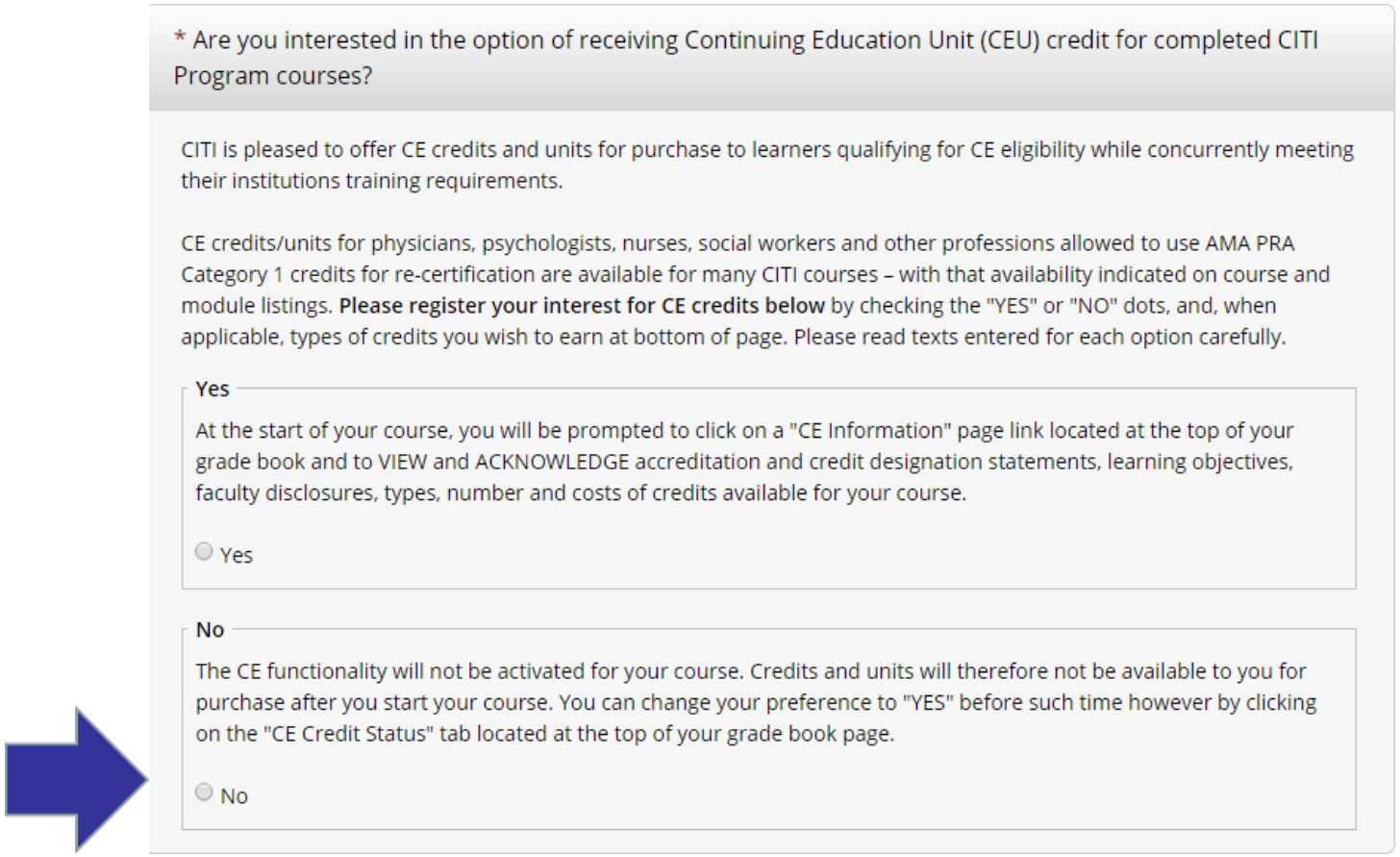
Step 7 – ตอบคำถามว่าจะเรียนเพื่อรับเครดิตหรือไม่



Click ‘No’.

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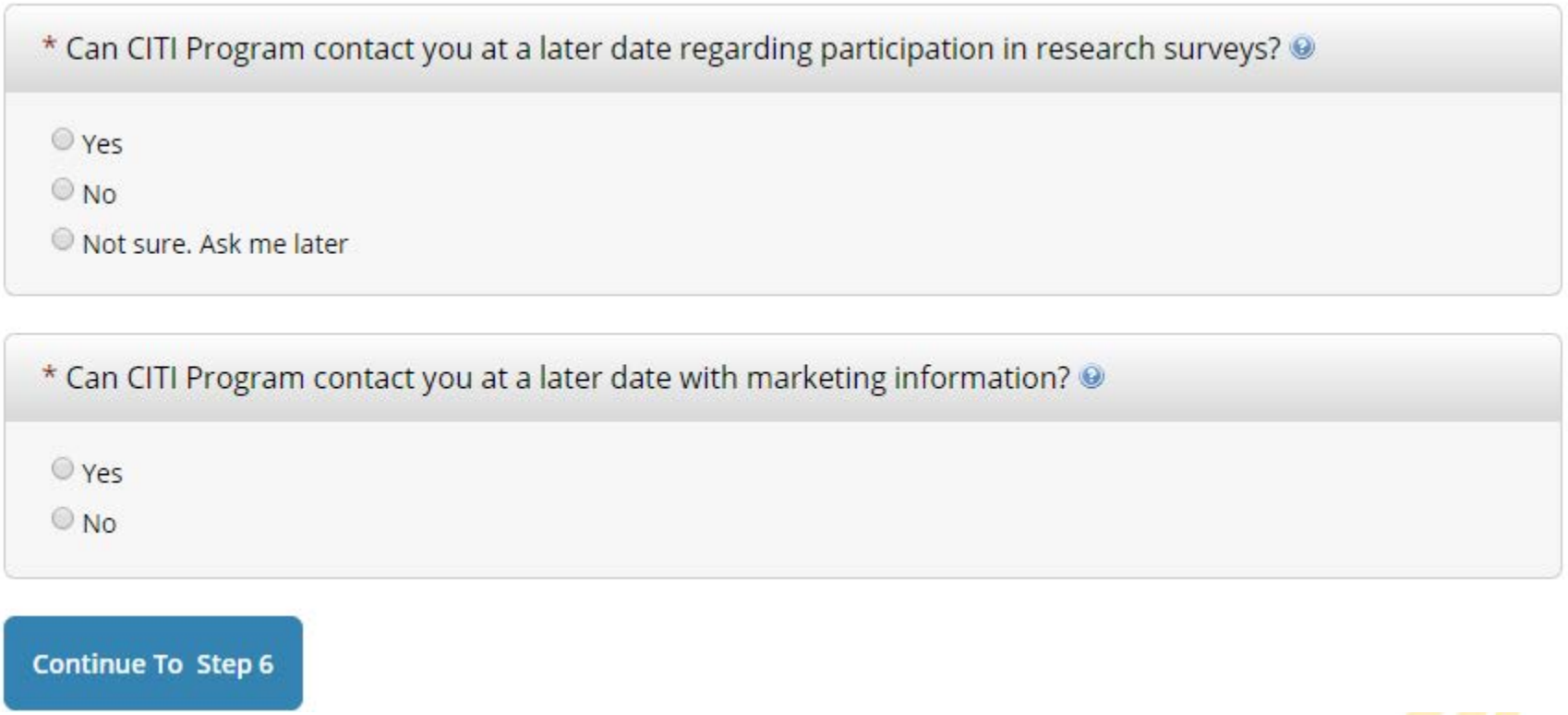
Step 7 – ตอบคำถามต่อให้จบ

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



Click to continue.

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Step 8 – ตอบคำถามต่อให้จบ แล้วเลือกบทบาทของผู้เรียน

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

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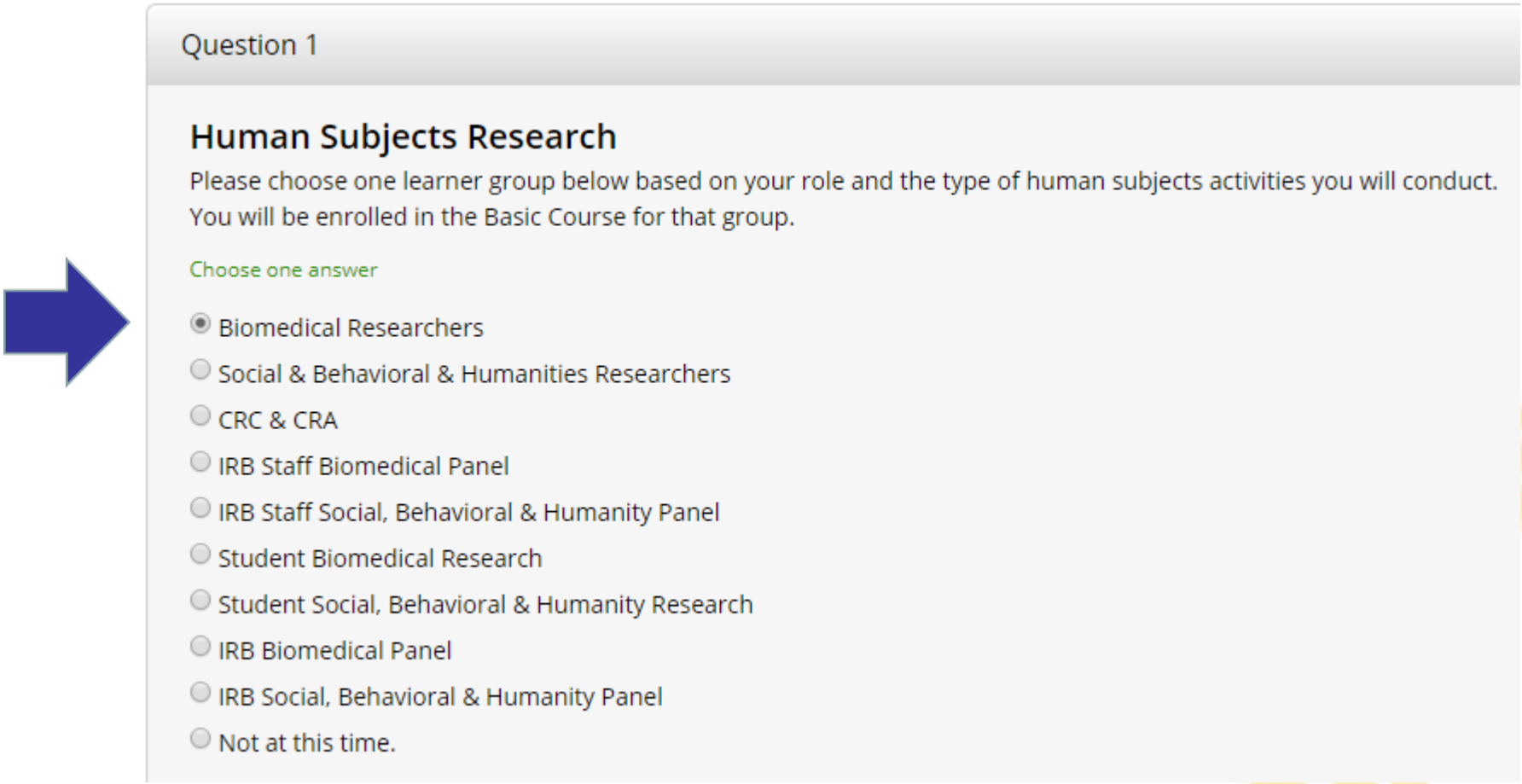
Step 9 – เลือก course

เลือก ‘Biomedical Researchers’.



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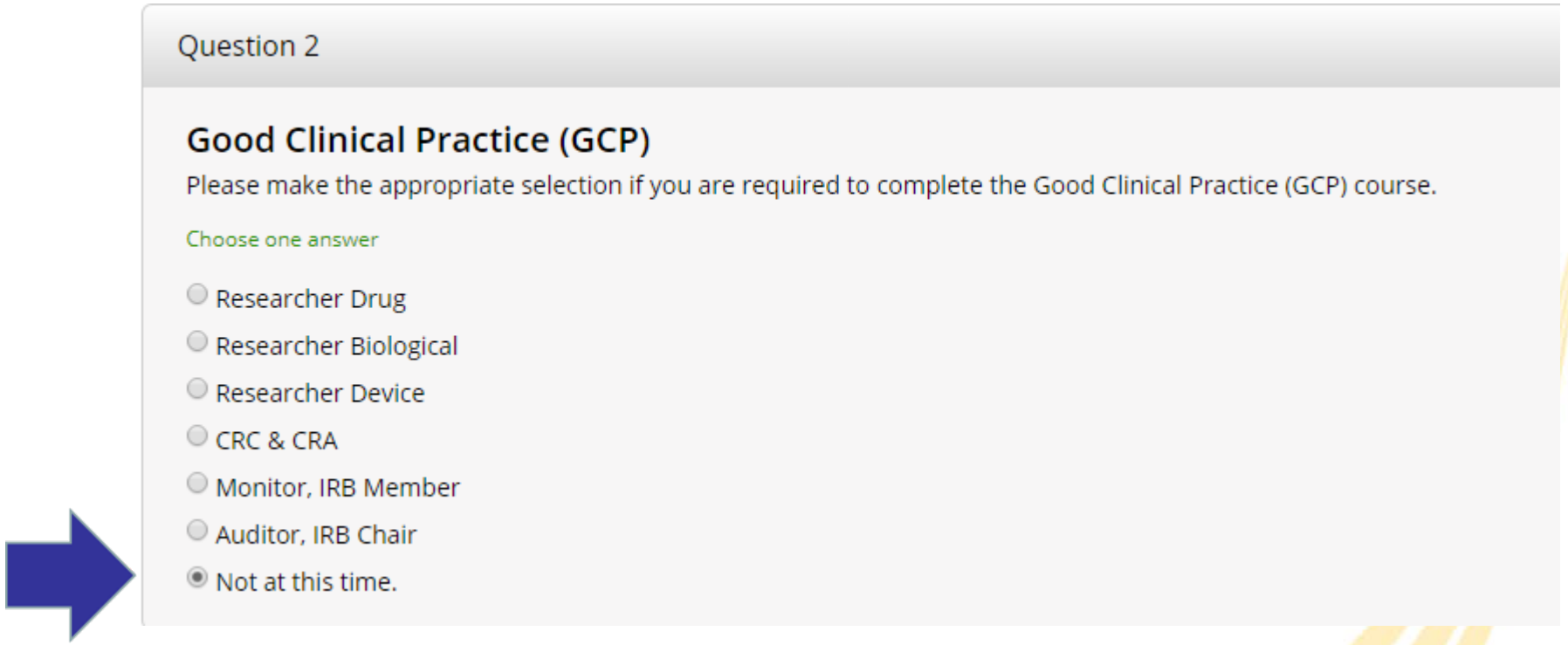
Step 9 – เลือก course (2)

ขณะนี้ยังไม่ต้องเลือกเรียน GCP course.

Choose ‘Not at this time’



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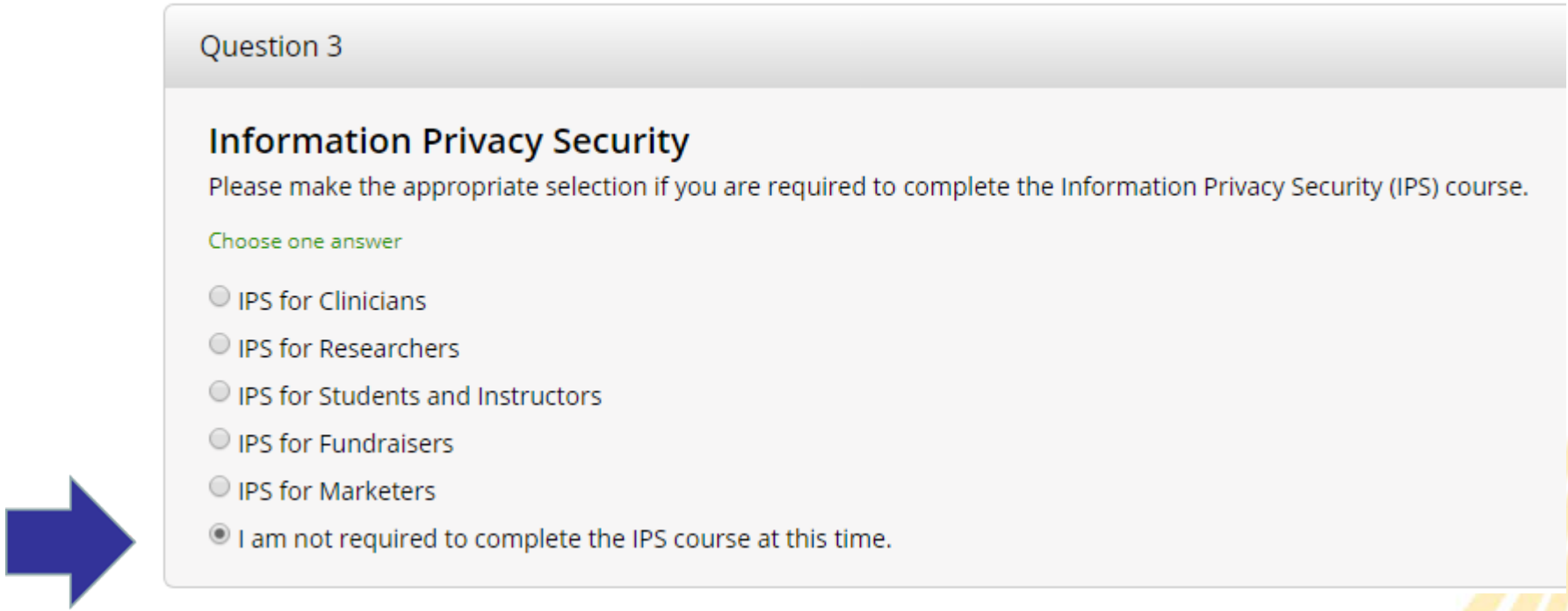
Step 9 – เลือก course (3)

ขณะนี้ยังไม่ต้องเลือกเรียน IPS course.

Choose ‘I’m not required…’



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Step 9 – เลือก course (4)

ขณะนี้ยังไม่ต้องเลือกเรียน RCR course

Choose ‘Not at this time’

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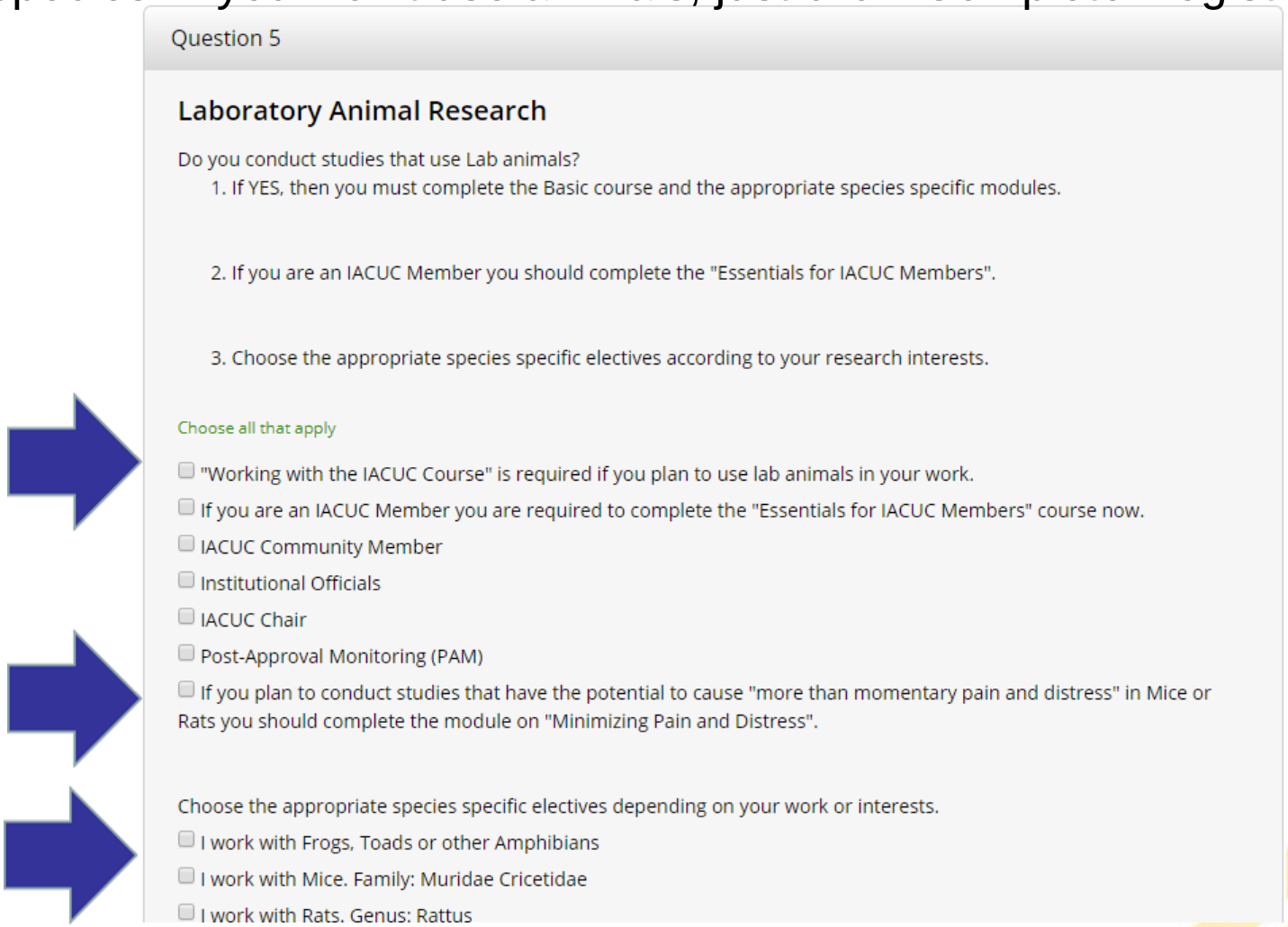
Step 9 – เลือก course (5)

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'.



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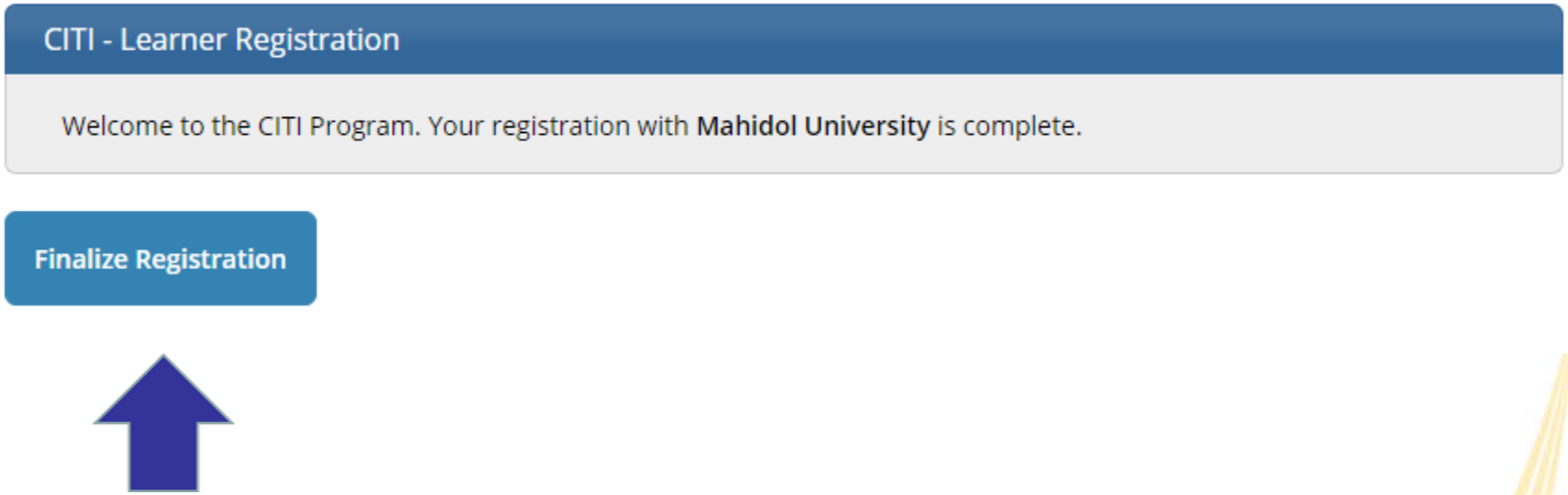
Step 10 – finalize

Click to finalize



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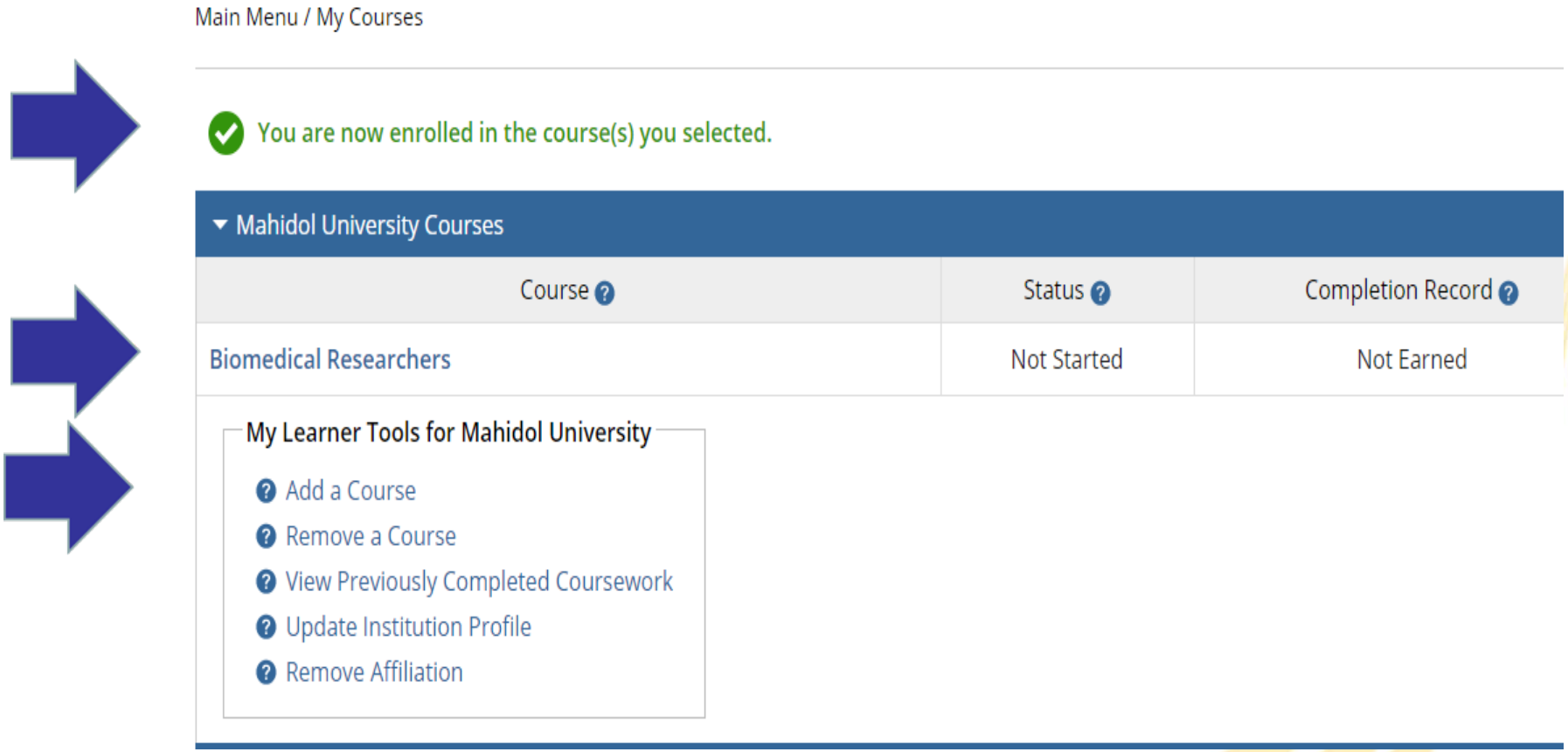
Step 11 – ‘My Courses’

ทำ bookmark หน้านี้ไว้. Click ‘Biomedical Researchers’ to start



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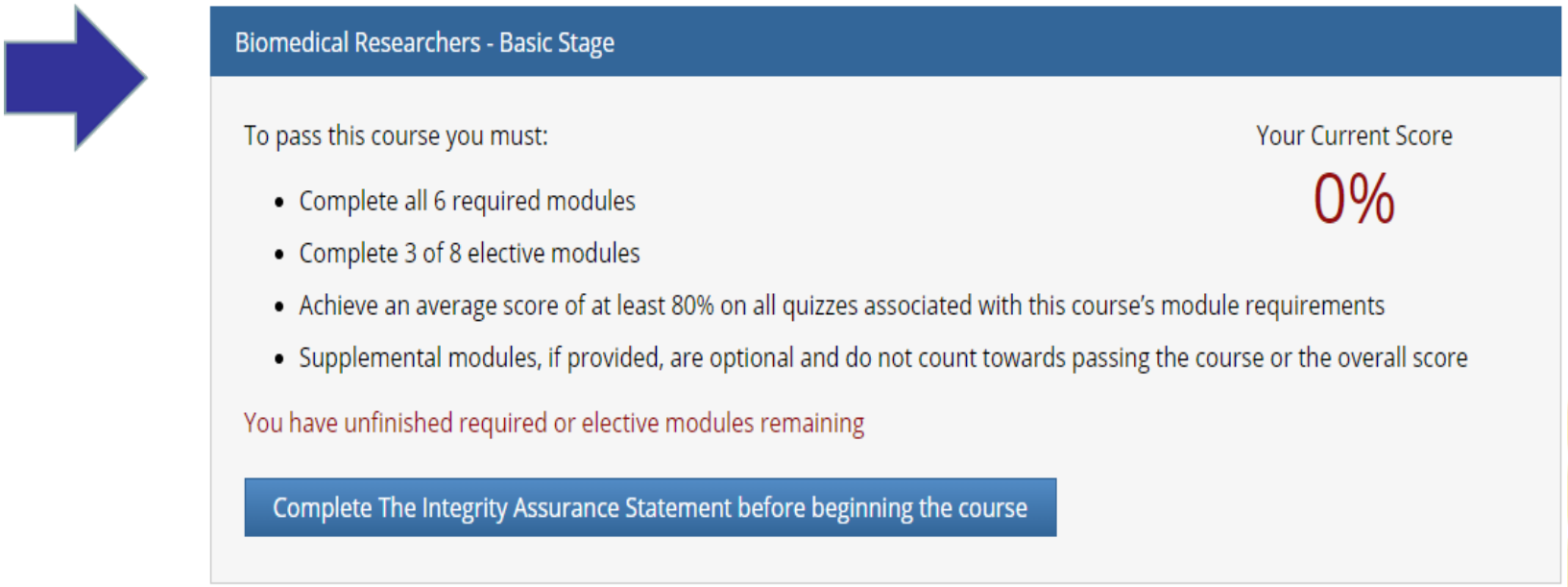
Step 12 – learn more about the course

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



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Step 13 – ข้อสัญญาและข้อตกลงในการทำแบบทดสอบ (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

Your Current Score
0%

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%)

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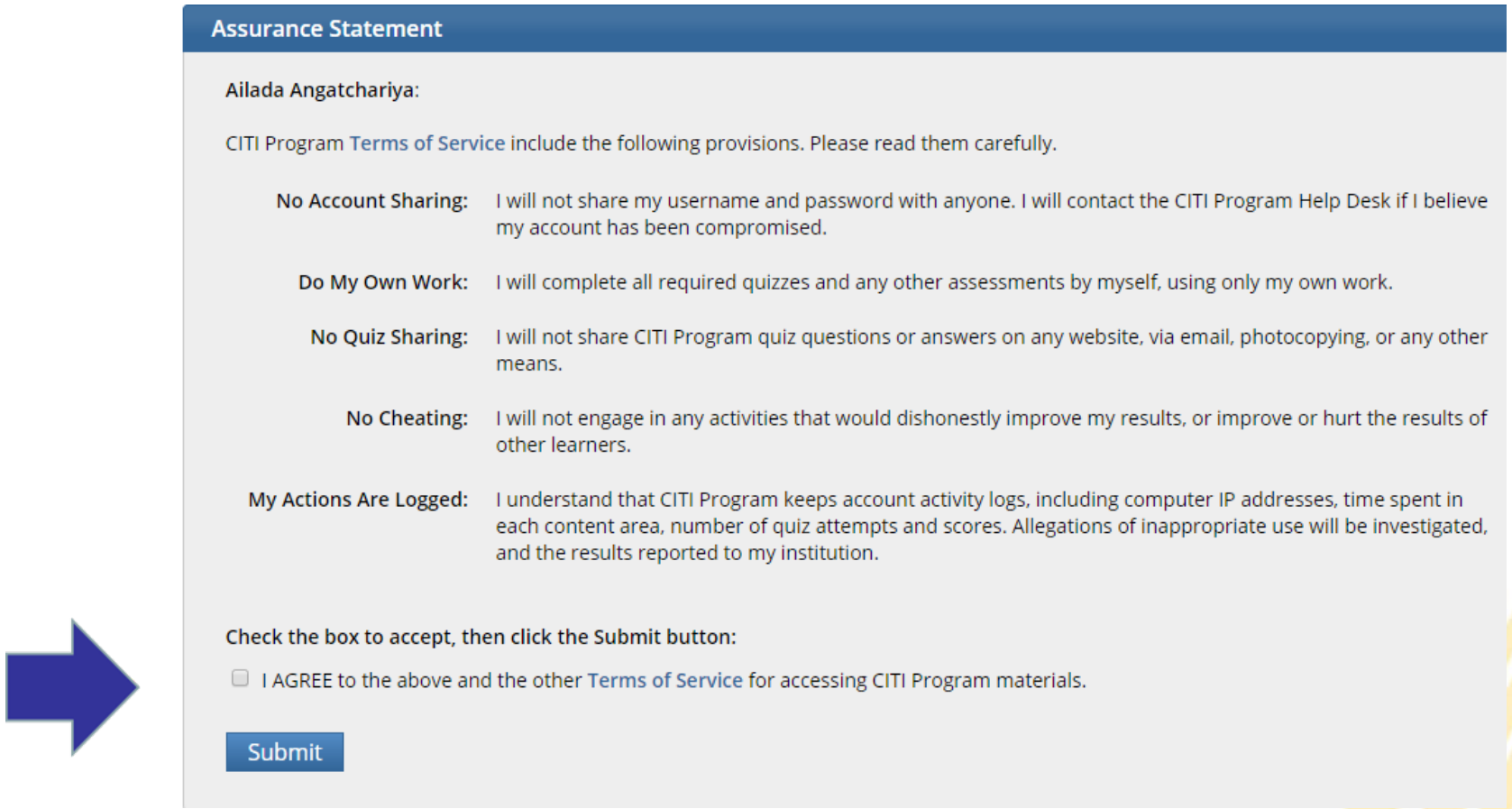
Step 13 – ข้อสัญญาและข้อตกลงในการทำแบบทดสอบ(2)

Click ‘Agree’ and ‘Submit’.



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Step 14 – start learning

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
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	Incomplete	0/0 (0%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	Incomplete	0/0 (0%)

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Inside a module (1)

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.

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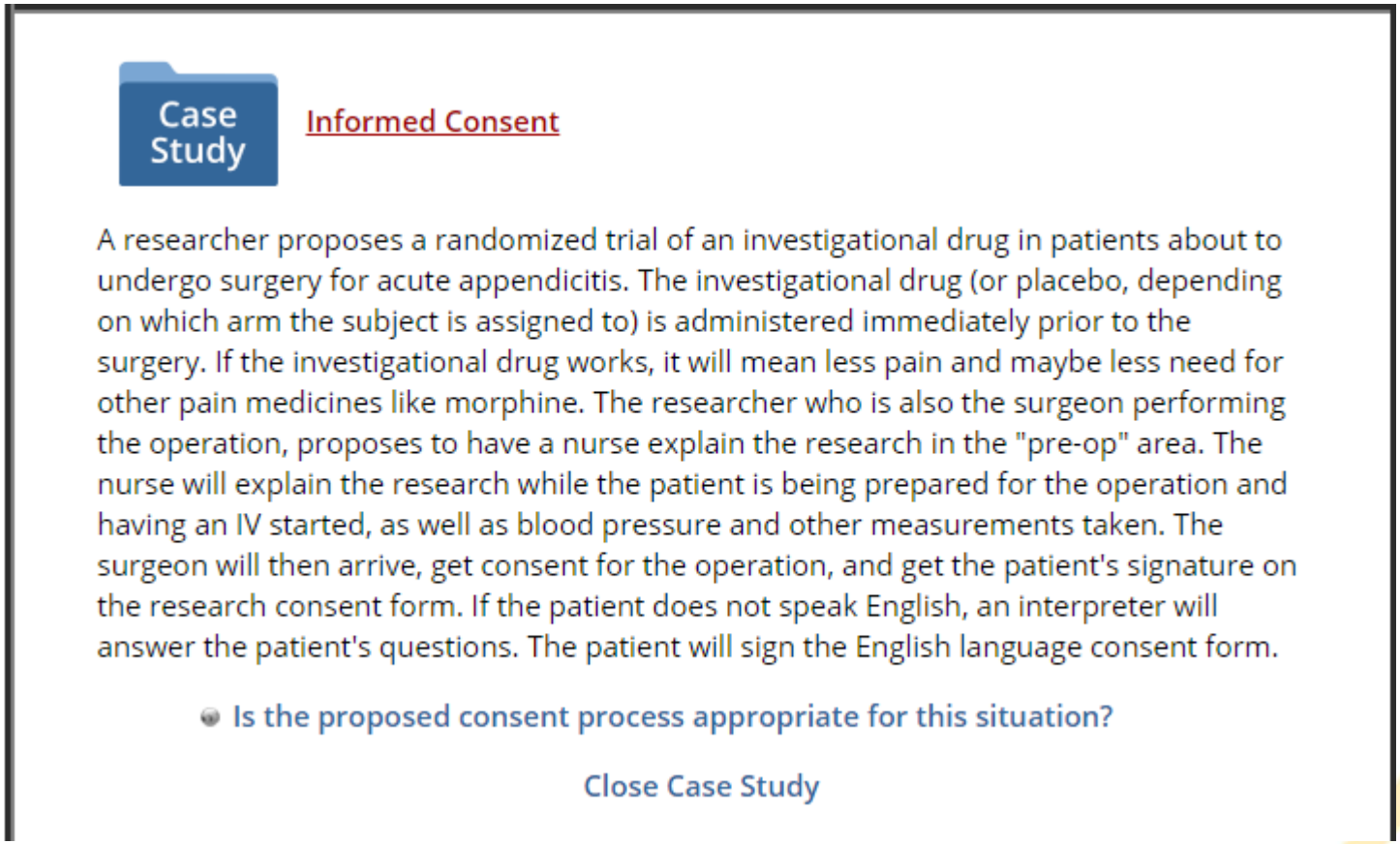
Inside a module (2)

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



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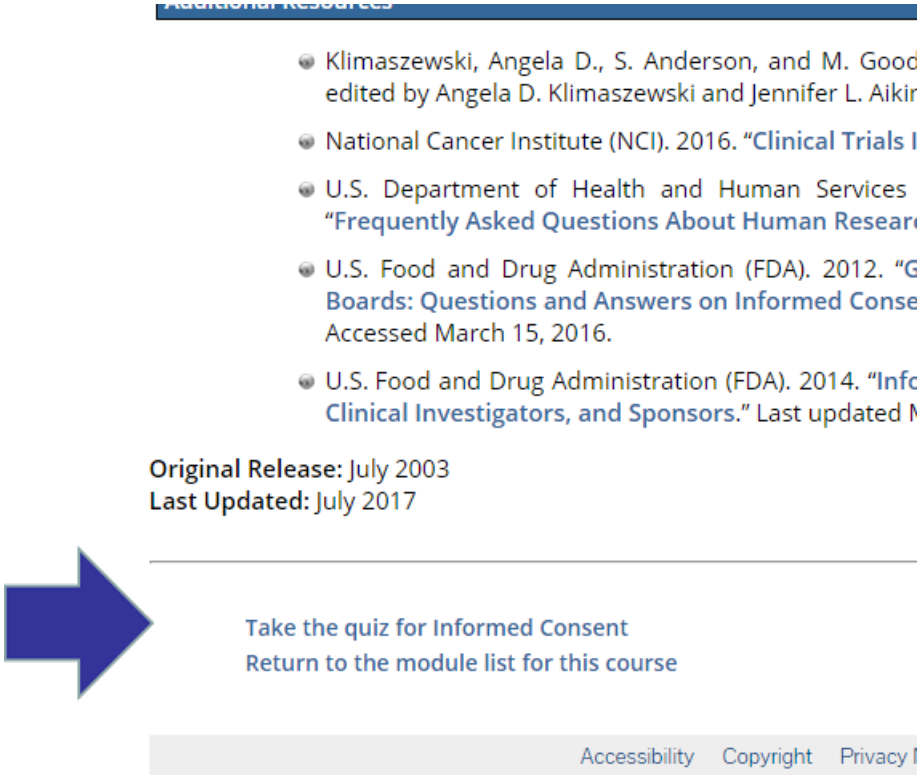
Inside a module (3)

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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Inside a module (4)

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

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Inside a module (5)

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.

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Inside a module (6)

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	I waive any possibility of compensation for injuries that I 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

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After the course

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 Requirements Report 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:** Nicola Ball (ID: 6447205)
- **Institution Affiliation:** Mahidol University (ID: 3292)
- **Institution Email:** nicola.bal@mahidol.ac.th
- **Institution Unit:** Faculty of Tropical Medicine

- **Curriculum Group:** Responsible Conduct of Research for Administrators
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR

- **Record ID:** 23835879
- **Completion Date:** 22-Aug-2017
- **Expiration Date:** 21-Aug-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

Example only

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Collaborative Research (RCR-Basic) (ID: 16598)	11-Jul-2017	5/5 (100%)
Conflicts of Interest (RCR-Basic) (ID: 16599)	17-Jul-2017	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	18-Jul-2017	5/5 (100%)
Financial Responsibility (RCR-Basic) (ID: 16601)	21-Aug-2017	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	21-Aug-2017	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	22-Aug-2017	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: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

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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.

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.

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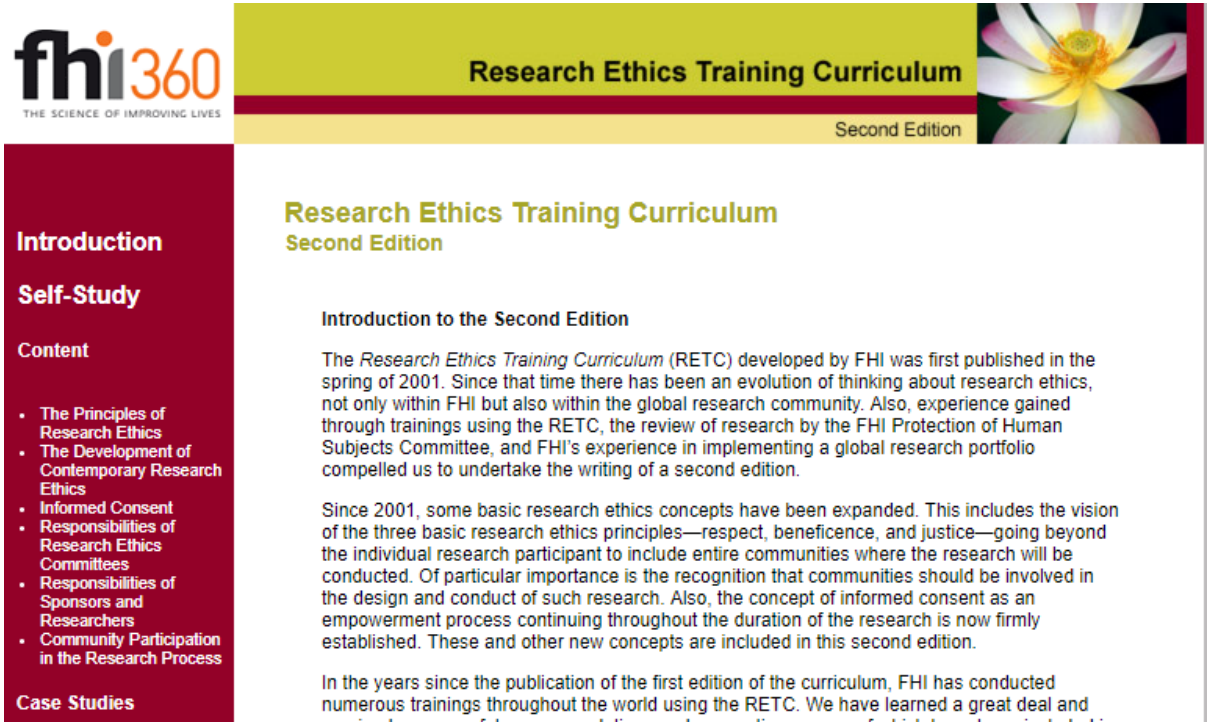
Other online courses and resources – fhi360

https://www.fhi360.org/sites/all//libraries/webpages/fhi-retc2/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

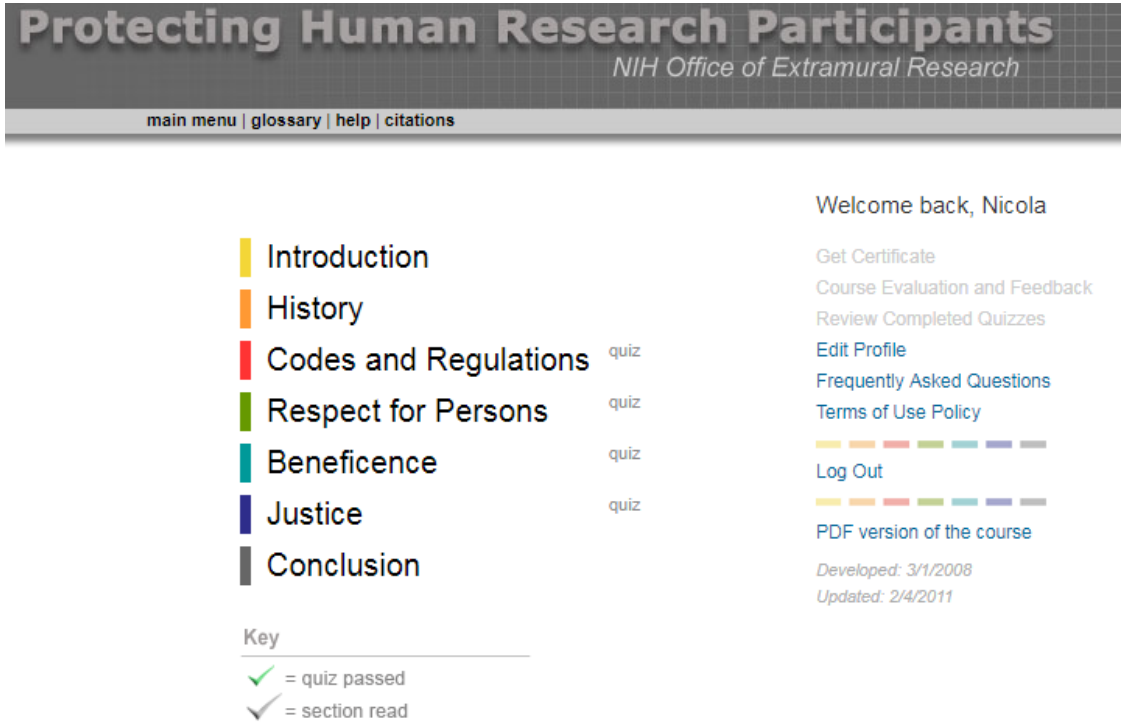
https://ori.hhs.gov/human-subject-research-0

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

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?