IRDI Collaborative Institutional Training Program

Research Ethics and Compliance Training for Staff

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Innovation
Imagination
Insight

PROGRAM OBJECTIVE

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to promoting the public's trust in the research enterprise by providing high quality, peer-reviewed, web-based educational courses in research ethics, compliance, and professional development education.

30
Training courses for diverse research background

100% Online
24/7 Access to all course materials and assessments

Internationally Recognized

What is this program about?

The International Medical University (IMU) has partnered with the Collaborative Institutional Training Initiative (CITI) to provide online training for IMU researchers in:

- Responsible Conduct of Research (RCR)
- Conflicts of Interest (COI)
- Information Privacy & Security (IPS)
- Human Subjects Research (HSR)
- Animal Care and Use (ACU)
- Good Clinical Practice (GCP)

What is IMU-CITI?

The IMU-CITI Program provides peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics. CITI courses are used worldwide by more than 2,200 organizations and more than 1 million learners around the world annually.

Responsible Conduct of Research (RCR)
3 Courses | 12 Modules

Conflicts of Interest (COI)
1 Course | 4 Modules

Information Privacy & Security (IPS)
4 Courses | 17 Modules

Human Subjects Research (HSR)
7 Courses | 93 Modules

Animal Care and Use (ACU)
11 Courses | 77 Modules

Good Clinical Practice (GCP)
4 Courses | 55 Modules

All applications and additional details are available on the Institute for Research, Development and Innovation (IRDI) website (http://imu.edu.my/irdi). Please email IRDI@imu.edu.my with any questions or for additional information.

Responsible Conduct of Research (RCR)

This course covers the core norms, principles, regulations, and rules governing the practice of research.

ABOUT THIS COURSE

RCR is increasingly viewed as an essential component of training, regardless of a researcher's source of funding. The term RCR is sometimes used interchangeably with research integrity or research ethics but these phrases do not always mean the same thing. RCR comprises the ethics of research practice and legal-regulatory compliance.

3 COURSES FOR DIFFERENT RESEARCH BACKGROUND

- Biomedical Responsible Conduct of Research
- Social and Behavioural Responsible Conduct of Research
- Humanities Responsible Conduct of Research

REQUIREMENTS:

All IMU faculty members and staff involved in research are required to complete the CITI RCR training.

LEARNING OBJECTIVES

By the end of this course, you should be able to:

- Explain why RCR is important for every researcher, regardless of discipline or career stage.
- Describe the standard RCR topic areas.
- Discuss key concepts and principles related to proper research practice.

TOPICS INCLUDE

- Authorship and Collaborative Research
- Conflicts of Interest and Data Management
- Mentoring and Supervision
- Peer Review
- Research Misconduct and Plagiarism
- Using Animal Subjects in Research
- Research Involving Human Subjects

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Conflicts of Interest (COI)

This course provides foundational training on the regulations associated with financial conflicts of interests in research.

ABOUT THIS COURSE

The public relies on the validity of research conducted at universities, academic medical centres, and other institutions. While nonfinancial factors affecting professional judgment are important, the focus of this course is on the potential for financial interests of individual researchers, and those of their immediate family members, to affect the design, conduct, or reporting of their research.

This course discusses the regulations on financial conflicts of interest and an investigator's responsibilities relating to the disclosure of "Significant Financial Interests."

It is designed to help learners satisfy training requirements associated with institutional regulations on financial conflicts of interest.

REQUIREMENTS:

All IMU faculty members and staff involved in research are required to complete the CITI COI training.

LEARNING OBJECTIVES

By the end of this course, you should be able to:

- Recognize various forms of financial conflicts of interest (FCOI) in research.
- Identify the members of the research team who are subject to FCOI requirements.
- Identify the significant financial interests (SFIs) that investigators are required to disclose to their institutions.

TOPICS INCLUDE

- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules
- Institutional Responsibilities as They Affect Investigators
- Conflicts of Commitment and Conscience
- Institutional Conflicts of Interest

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Information Privacy & Security (IPS)

This course covers the principles of data protection, healthcare-related privacy and information security, and the educational records and data-related security.

ABOUT THIS COURSE

The IPS course is designed to help ensure health privacy compliance, quality assurance, and risk reduction. IPS consists of three courses on Health Privacy (focusing on HIPAA), Information Security, and the Family Educational Rights and Privacy Act (FERPA), which can be utilized based on organizational needs.

4 COURSES FOR DIFFERENT RESEARCH BACKGROUND

- IPS for Clinicians
- IPS for Researchers
- IPS for Students and Instructors
- Family Educational Rights and Privacy Act (FERPA)

REQUIREMENTS:

All IMU faculty members and staff involved in research are required to complete the CITI IPS training.

LEARNING OBJECTIVES

By the end of this course, you should be able to:

- Describe the basic privacy protections for health information and other legal-regulatory and non-government sources.
- Identify the duties imposed on persons with access to protected health information (PHI) in order to fulfil those privacy requirements.
- Describe FERPA's requirements and how the law protects students' educational records.
- Describe basic techniques of data and device security.

TOPICS INCLUDE

- Health Privacy
- Information Security
- Educational Rights and Privacy

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Human Subjects Research (HSR)

This course provides foundational training in human subjects research, ethical issues, and current regulatory and guidance information.

ABOUT THIS COURSE

The HSR courses are intended for anyone involved in research studies with human subjects, or who have responsibilities for setting policies and procedures with respect to such research, including Institutional Review Boards (IRBs).

4 COURSES FOR DIFFERENT RESEARCH BACKGROUND

- Biomedical Research Investigators
- Research with data or laboratory specimens-ONLY
- Social & Behavioural Research Investigators
- IRB Members
- Public Health Research

REQUIREMENTS:

All IMU faculty members and staff involved in human subjects research must complete the CITI HSR Course prior to IMU-JC Review

LEARNING OBJECTIVES

By the end of this course, you should be able to:

- Define research with human subjects
- Describe and distinguish between vulnerable populations in research
- Apply the principles to human subjects research

TOPICS INCLUDE

- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Records-Based Research
- Genetic Research in Human Populations
- Vulnerable Subjects
- Avoiding Group Harms
- Internet-Based Research

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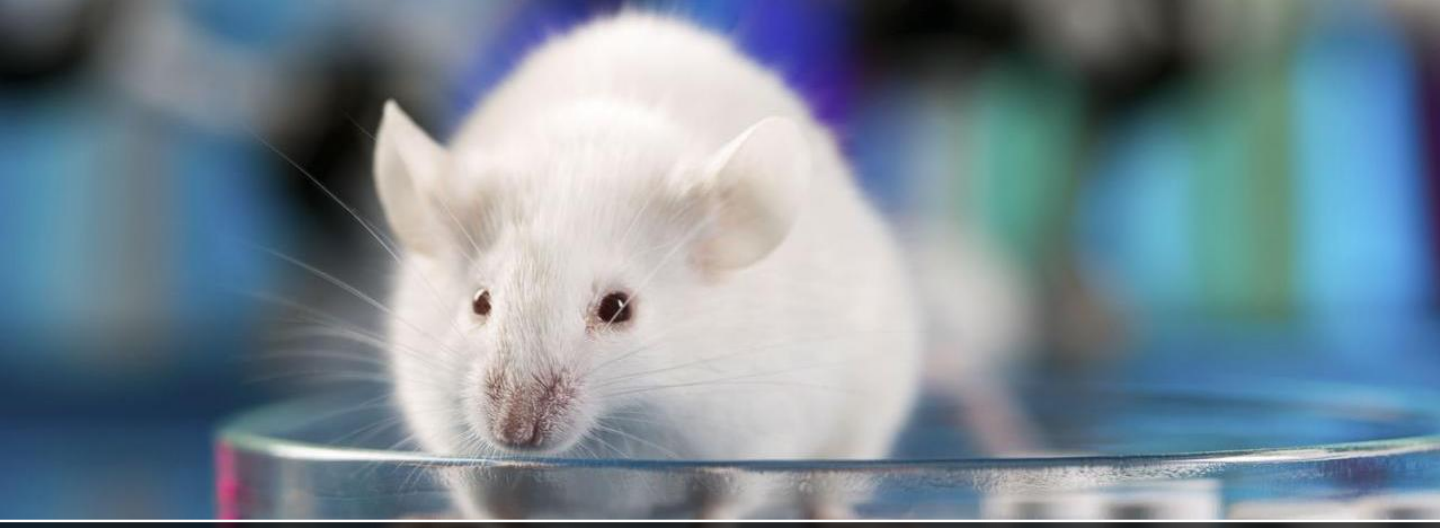

Animal Care and Use (ACU)

This course covers the general principles of the ethical care and use of animals in research, training, and testing.

ABOUT THIS COURSE

The ACU courses are designed to meet requirements for basic training in the humane care and use of animals. The courses are intended to help investigators work more productively. Additional courses are available for individuals seeking training on post-procedure care and post-approval monitoring or wildlife research. Courses on working with specific animal types are also included.

4 SEPARATE COURSES FOR DIFFERENT RESEARCH AREAS

- ACU for Researchers
- ACU for Animal Technicians
- ACU for Research Administrators and Staff
- ACU for Students Working with Animals

REQUIREMENTS:

All IMU faculty members and staff involved in animal care, use or treatment must complete the CITI ACU course prior to IMU-JC approval of their protocol.

LEARNING OBJECTIVES

By the end of this course, you should be able to:

- Summarize an individual's responsibilities when using animals in research, teaching, and testing.
- Incorporate reduction, replacement, and refinement (the "3 Rs") into research, teaching, and testing activities.
- Use appropriate pre/post procedural techniques, monitoring, and care.

TOPICS INCLUDE

- Investigator Responsibility
- Minimizing Sources of Nonexperimental Variation
- Systematically Monitoring for Pain and Distress
- Alleviation of Pain and Distress
- Wildlife Research

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Good Clinical Practice (GCP)

This course consists of basic courses that provide essential good clinical practice training for research teams involved in clinical trials of drugs, biologics, and devices, as well as those involved in behavioural intervention and social science research studies.

ABOUT THIS COURSE

The GCP course covers International Council for Harmonisation (ICH) E6 Good Clinical Practice (GCP) guideline essential topics for clinical trials with drugs and biologics. It describes the responsibilities and expectations for the conduct, monitoring, reporting, and documenting of clinical trials.

4 COURSES FOR DIFFERENT RESEARCH BACKGROUND

- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
- GCP for Clinical Investigations of Devices
- GCP - Social and Behavioral Research Best Practices for Clinical Research

REQUIREMENTS:

All IMU faculty members and staff involved in clinical studies must complete the CITI GCP course prior to IMU-JC approval of their protocol.

TOPICS INCLUDE

- Reviewing ICH GCP standards
- Identifying investigator and sponsor obligations
- Discussing new drug development
- Describing how to detect and report adverse events
- Auditing and monitoring expectations

Note:

Although the Good Clinical Practice (GCP) course offered under CITI Program is recognized in many countries, Malaysia is not one of it. To conduct clinical trial, researchers are required to complete the Malaysian GCP Training and pass the Malaysia GCP examination.

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FAQs

Why does IMU require researchers to complete the CITI Program training?

By requiring our faculty and staff to complete the CITI Program training, we are conforming to best practices concerning the ethical and responsible conduct of research.

Who must complete the training?

Anyone who is a principal investigator (PI) or a collaborator involved in research activities affiliated to IMU must complete the training. The PI on a project is responsible for ensuring that all collaborators/investigators have completed the training.

If I attended the Supervisory and Research Ethics Workshop organized by IRDI previously, will I need to complete this training again?

Maybe or maybe not. If you have attended the IRDI's Supervisory and Research Ethics Workshop, you may be exempted from taking the CITI Course on Responsible Conduct of Research (RCR) and Human Subjects Research (HSR). However, you will still need to take other CITI's Courses as deemed required based on the type of research that is being proposed. If you have any questions or concerns, please contact the Research Management Center (RMC).

Is the CITI's Good Clinical Practice (GCP) course recognized in Malaysia?

No. Although the Good Clinical Practice (GCP) course offered under CITI Program is recognized in many countries, Malaysia is not one of it. To conduct clinical trial, researchers are required to complete the Malaysian GCP Training and pass the Malaysia GCP examination.

Do students require to complete the training?

No. Students are encouraged to take the student version of the CITI Program offered by the IMU Center for Lifelong Learning (ICL) as part of their Continuing Professional Development. Upon completion, the student will receive an internationally recognized Certificate of Completion from CITI. A registration fee may apply.

When must the training be completed?

Effective 1st January 2021, all IMU researchers must complete the CITI Program training prior to submitting an IMU-JC proposal. When submitting an IMU-JC proposal, the PI is required to certify that all individuals on the proposal have completed the training.

If completion of the training prior to submission of an IMU-JC proposal poses a significant hardship, the PI on the project should contact the IMU-JC to discuss the possibility of an extension on the training requirement.

What does the training consist of?

The CITI Program training consists of a number of selected courses based on the needs of our community. The courses are constructed of modules, and many different modules are available for these courses. Each module is followed by a short quiz, which must be completed before you can proceed to the next module. In addition to the required modules, supplemental modules are available. You can complete any of the supplemental modules that you wish to complete. Researchers engaged in research with particular populations and/or in particular settings may require to complete certain supplemental modules.

FAQs

Can I use the CITI's course Completion Certificate as evidence during my annual appraisal?

Yes. Training in research ethics and compliance is qualified as part of the Individual Development Plan (IDP) under IMU Human Resource Policy.

How do I complete the training?

The CITI Program training is an on-line course. It can be completed from any device with internet access. You can use whichever browser you prefer. You will be required to create an account.

A step-by-step instructions on how to create your account on CITI and begin the training is available at http://imu.edu.my/irdi.

How often do I need to do the CITI training?

The CITI Program training certification is valid for three (calendar) years. After three years, you will be required to complete shorter CITI Program refresher courses before you can submit a proposal or request continuation of IMU-JC approval already received.

How do I know if my CITI training certification has expired? How do I complete the Refresher Courses?

You can determine the date of your training certification by looking at your "Completed Courses" on the CITI website. In addition, approximately 90 days prior to the due date for your re-certification on a course, a refresher course will automatically appear among your courses on the CITI website. You will then complete the course in the same manner that you complete any CITI course.

What happens if I don't complete the refresher courses for recertification of my CITI training?

If you are submitting a new proposal or a request for the continuation of your IMU-JC approval on an existing proposal, your certification must be up to date for the IMU-JC to consider your proposal or request. If your certification expires after you have received approval of your proposal or request for continuation, you are expected to complete the recertification in a timely fashion. Failure to do so may result in the withdrawal of your IMU-JC approval.

How long does the training take to complete?

The training for each course takes approximately 2 hours. These time estimates are based on pilot testing; how long any particular individual takes to complete the course varies.

Must I complete the quizzes? What grade do I need to earn on the quizzes?

You must complete all of the quizzes for the required modules. You will not be able to proceed to the next module without completing the quiz.

You must earn an average overall of 80% on the quizzes to be certified as having completed the training. You can earn less than 80% on a specific quiz to be certified as long as your overall average is 80%.

Will the training cost me money to complete?

No. As IMU staff, you do not pay anything. IRDI pays a yearly subscription fee that allows the institution to provide this service to all members of the community.

What courses should I take?

The specific course will depend on your study area and activities. Please, see the following chart for more information:

Research Training Courses	Research NOT involving human subjects or animals	Research involving human subjects						Research involving animals	
		Clinical trials	Research involving collection of specimen	Research involving collection of existingclinical data	Research involving survey / questionnaire	Research involving collection of students' data	Research involving humanitarian activities (e.g. IMU Cares)	Involving lab animals	Involving wild-life
Responsible Conduct of Research (RCR)									
Biomedical Responsible Conduct of Research	●	●	●	●				●	●
Social and Behavioural Responsible Conduct of Research					●	●			
Humanities Responsible Conduct of Research							●		
Conflicts of Interest (COI)	●	●	●	●	●	●	●	●	●
Information Privacy and Security (IPS)									
Information Privacy & Security for Researcher	●	○	○	○	●	●	●	●	●
Information Privacy & Security for Clinician		●	●	●	○	○	○		
Information Privacy & Security for Students and Instructors	○	○	○	○	○	○	○	○	○
Family Educational Rights and Privacy Act (FERPA)						●			
Human Subjects Research (HSR)									
HSR for Biomedical Research		●	○	○					
HSR for Biomedical Data or Specimens Only Research		○	●	●					
HSR for Social-Behavioural-Educational (SBE) Research					●	●	●		
Public Health Research				●	●	●	●		
HSR for IRB Members									
IRB Chair									
Institutional/Signatory Official: Human Subjects Research									
Good Clinical Practice (GCP)									
Clinical Trials with Investigational Drugs and Biologics (ICH Focus)		●	●	●					
Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)		●							
Clinical Investigations of Devices		●							
Social and Behavioural Research Best Practices for Clinical Research					●	●	●		
Animal Care and Use (ACU)									
Working with the IACUC								●	●
Essentials for IACUC Members								●	●
IACUC Community Member								●	●
Post-Approval Monitoring (PAM)								●	●
Working with Mice in Research								○	
Working with Rats in Research								○	
Reducing Pain and Distress in Laboratory Mice and Rats								○	
Working with Rabbits in Research								○	
Working with Guinea Pigs in Research								○	
Working with Hamsters in Research								○	
Wildlife Research								○	●

● Required ○ Optional

CITI Training Registration and Curriculum Setup Instructions

To register for a new CITI Training account:

1. Go to www.citiprogram.org and click Register to create an account.
2. Under Select Your Organization Affiliation, in the Search for Organization box, enter: International Medical University.
3. Follow the registration instructions, entering your IMU email address in the required field. You will have the option to add a second email address.
4. Upon completing registration, you will be directed to the Main Menu/My Courses page.

To add courses to your CITI Training curriculum:

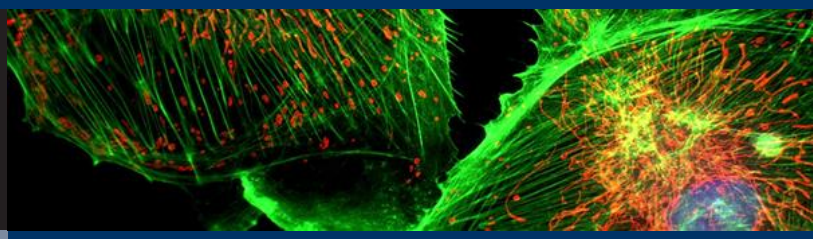
1. From Main Menu/My Courses page, under the heading My Learner Tools for International Medical University, click Add a Course.
2. Answer the setup questionnaire to select the course(s) you require.
3. Click Submit. The selected course(s) will now appear in your course list on the Main Menu/My Courses page.
4. Click on the course name to begin the course.
5. Save copies of your course completion records as documentation of your training(s).

For assistance, please contact:

Institute for Research, Development and Innovation (IRDI)
Tel : 03-2731 7044
Fax : 03-8656 7299
Email: IRDI@imu.edu.my

IRDI Collaborative Institutional Training Program

Research Ethics and Compliance Training



Contact Information

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All applications and additional details will be available on the IMU Institute for Research, Development and Innovation (IRDI) website (http://imu.edu.my/irdi). Please email IRDI@imu.edu.my with any questions or for additional information.

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