IRDI Collaborative Institutional Training Programme

Research Ethics and Compliance Training

CITI PROGRAM

IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Innovation
Imagination
Insight

PROGRAMME 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.

54
Training courses for diverse research background

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

Internationally Recognized

Is this programme right for me?

CITI Programme offers research ethics, compliance, and professional development education on a number of subjects for various audiences, including researchers, students and faculty, IRB members, and research administrators. The online courses are used worldwide by over 2,200 organizations and more than 1 million learners around the world annually.

Earn a Certificate. What are my options?

The programme is offered as a series of courses. When you subscribe to the programme, you are automatically subscribed to all the courses (subject to a one-time activation fee). Upon completion of each course, you will receive a Completion Report and a Completion Certificate.

ONE-TIME SUBSCRIPTION FEE

IMU Student	RM 200
IMU Alumni	RM 200

Research Methodology
4 Courses | 53 Modules
NEW

Coronavirus (COVID-19) Resources
4 Course | 13 Modules
NEW

Responsible Conduct of Research (RCR)
3 Courses | 14 Modules

Human Subjects Research (HSR)
12 Courses | 83 Modules

Animal Care and Use (ACU)
25 Courses | 68 Modules

Information Privacy & Security (IPS)
3 Courses | 23 Modules

Good Clinical Practice (GCP)
4 Courses | 55 Modules

All applications and additional details will be available on the IMU Center for Lifelong Learning website (www.imu.edu.my/icl). Please email icl@imu.edu.my with any questions or for additional information.

Research Methodology

Responsible Conduct of Research and Supervision

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

ABOUT THIS COURSE

Responsible conduct of research (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 is suitable for any person involved in research, ranging from upper-level undergraduates to established faculty. Particular emphasis is given to the educational needs of graduate students and postdoctoral researchers.

LEARNING OBJECTIVES

- 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.

COURSE CONTENT

- Introduction to RCR
- Authorship
- Collaborative Research
- Conflicts of Interest
- Data Management
- Mentoring
- Peer Review
- Plagiarism
- Reproducibility of Research Results
- Research Involving Human Subjects
- Using Animal Subjects in Research
- Research Misconduct
- Financial Responsibility
- Research, Ethics, and Society

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Research Methodology

Communicating Research Findings

This course focuses on effective practices, guidelines, and strategies for communicating and presenting research findings.

ABOUT THIS COURSE

Researchers have a range of ethical obligations when designing and conducting their research activities. These obligations also pertain to how researchers share their findings with others. This course covers two main topic areas in the realm of sharing research findings. The first module focuses on practices and guidelines for presenting research findings to other researchers. The second module focuses on strategies for more effectively communicating research to the public.

LEARNING OBJECTIVES

- Discuss why accurate and clear presentation of research findings is important to the research community and public.
- Explain challenges associated with the clear presentation of research findings.
- Describe approaches for making research findings understandable to different audiences.
- Describe "dos" and "don'ts" for representing data in charts, tables, and graphs.
- Describe "dos" and "don'ts" for presenting digital image data in figures.
- Compose legends that provide clarity to the research findings presented in a figure or table.
- Formulate good research practices to reduce the likelihood of improper image handling or other inappropriate data presentation practices.
- Differentiate between appropriate data manipulation practices and those associated with research misconduct.

COURSE CONTENT (2 modules)

- Communicating with the Public
- Presentation of Research Findings

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Research Methodology

Research Study Design

This course provides learners with an understanding of how to improve study design, collect and analyse data, and promote reproducible research.

ABOUT THIS COURSE

The Research Study Design course provides learners with an introduction to research study design. This course is valuable to university undergraduate and graduate students who are taking a classroom research study design course or who need a refresher on a specific aspect of research design. Research team members and Institutional Review Board members who may need an overview or refresher on research design concepts will also find the course meaningful.

LEARNING OBJECTIVES

- Provide overview of formulating a research question and the steps associated with developing a hypothesis.
- Discuss the different types of observational and interventional research designs.
- Provides an overview of statistical reasoning, hypothesis testing, and research design
- Provides an overview of survey research design, with a focus on developing and pilot testing the survey instrument.
- Provides an overview of qualitative research and differences among the major qualitative research designs.

COURSE CONTENT

- Introduction to Scientific Research
- Observational Research
- Interventional Research
- Quantitative Research
- Survey Research: Designing the Instrument
- Survey Research: Conducting the Research
- Qualitative Research Methods
- Mixed Methods Research
- Data Management
- Reproducibility of Research Results

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Research Methodology

Essentials of Statistical Analysis

Teaches learners the essentials of statistical analysis.

ABOUT THIS COURSE

This course provides a comprehensive introduction to statistical analysis, including foundational and advanced topics.

LEARNING OBJECTIVES

- Introduces the concepts of sampling, representativeness, and statistical inferences.
- Introduces parametric methods used to compare scores across two or more groups.
- Reviews parametric and nonparametric methods for determining the strength of association between two sets of numerical scores.
- Discuss the different types of predictive relationships and reviews methods for determining the relationship between a predictor and an outcome.
- Reviews methods for examining the relationships of multiple predictors to a single outcome variable.

COURSE CONTENT (27 modules)

- Introduction to Statistics
- Sensitivity and Specificity
- Distribution and Probability
- Normal Distribution and Z-Scores
- Standard Error and Type I-II Errors
- Comparing Two Independent Means
- Nonparametric Methods for Paired Sample Data
- Analysis of Variance
- Proportions
- Comparing Two Independent Proportions
- Contingency Tables and Chi-Square Tests
- Correlations
- Simple Linear Regression
- Multiple Regression

CITI PROGRAM

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Coronavirus (COVID-19) Resources

COVID-19: Back to Campus (2020-2021)

This course is to train staff, students, and faculty on COVID-19 safety for their return to campus.

ABOUT THIS COURSE

CITI Program and the Association of American Medical Colleges (AAMC) have brought together recognized institutions to contribute and present materials in preparation for the return to campuses.

LEARNING OBJECTIVES

- Provides an introduction to COVID-19, including an overview of zoonotic infections, coronaviruses, and the symptoms and risk factors associated with COVID-19.
- Provides an overview of how COVID-19 spreads and prevention strategies.
- Reviews transmission information as a foundation for an in-depth review of social distancing guidelines across different settings (public spaces, elevators/stairwells, and laboratories), hygiene best practices, face coverings in general settings.
- Review of techniques to consider for overall mental health and personal wellbeing.
- Provide an overview of a number of important areas related to working with patients who are infected or suspected with COVID-19.

COURSE CONTENT

- COVID-19: An Introduction
- COVID-19: Prevention Strategies
- COVID-19: Moving Forward
- COVID-19: Human Subjects Research
- COVID-19: Safe Lab Reactivation (Animal Research)
- COVID-19: Working with Patients Infected or Suspected with COVID-19

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IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Coronavirus (COVID-19) Resources

COVID-19: Insights for Higher Ed Leaders

Gain insights to guide strategic planning surrounding COVID-19 operations in Higher Education.

ABOUT THIS COURSE

Through interviews with leaders across various universities and colleges, we discuss the strategies, lessons learned, and insights regarding operations in response to COVID-19. Learn about reopening strategies for and how these institutions are planning to provide a healthy, safe, and productive environment on their campuses in 2021.

TOPICS INCLUDE

- General health and safety operations
- Student financial and academic support services
- Supporting a campus community's mental health
- Methods for setting up and administering onsite COVID-19 testing
- Methods for contact tracing in the university setting
- Strategically planning ahead for health and safety operations in 2021
- Strategies for continuing research and lab operations during COVID-19
- Additional health and safety risk mitigation strategies regarding COVID-19 on college campuses
- Methods for restarting field research operations
- Safety measures for research and lab operations during COVID-19

COURSE CONTENT

- COVID-19 Strategic Planning: Insights and Advice for 2021
- COVID-19 Strategic Planning: Campus Health and Safety Operations
- COVID-19 Strategic Planning: Restarting and Continuing Research and Lab Operations

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Coronavirus (COVID-19) Resources

Remote Contact Tracing

Train individuals to conduct remote contact tracing for COVID-19 according to an established protocol and using evidence-based practices.

ABOUT THIS COURSE

Contact tracing is vital in stopping the spread of COVID-19. Contact tracers communicate with infected individuals as well as notify and monitor their recent contacts. Stopping one case from spreading COVID-19 can break the chain of transmission. This three-webinar course, prepares individuals for the role and responsibilities of remote contact tracing.

LEARNING OBJECTIVES

- Describe the fundamentals of contact tracing and its public health role in preventing the spread of infectious diseases.
- Describe the clinical course of COVID-19 infection.
- Identify COVID-19 transmission and methods to prevent spread.
- Discuss the three types of COVID-19 testing.
- Describe the types of treatments for COVID-19.
- Review contact tracing steps.
- Outline evidence-based practices for remote communication and interviewing when investigating cases or following up with contacts.
- Contrast the public health need for contact tracing with the individual's need for privacy and autonomy.
- Define confidential information, and outline strategies for ensuring data privacy and protection.
- Review the legal basis and limits for social distancing, quarantine, and isolation.

COURSE CONTENT

- Remote Contact Tracing Basics for COVID-19
- Investigating and Tracing a Case's Contacts
- Contact Tracing Ethics and Responsibilities

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Coronavirus (COVID-19) Resources

Participating in Vaccine Research

Learn about what to expect when participating in vaccine research.

ABOUT THIS COURSE

Before participating in vaccine research, you should learn about what to expect and where to find more information. This webinar discusses vaccine research and overviews what to expect as a participant. The presenter identifies questions you should ask and things to consider before deciding to participate. Further, she describes some different ways to find a vaccine research study to join.

LEARNING OBJECTIVES

- Describe what research is.
- Identify what a vaccine is.
- Discuss different efforts to create a COVID-19 vaccine.
- Review the role, rights, and responsibilities of a subject in a research study.
- Consider reasons to participate or not in research.
- Identify some ways to find a vaccine trial to join.

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Responsible Conduct of Research (RCR)

Biomedical Responsible Conduct of Research

This course covers the core norms, principles, regulations, and rules governing the practice of biomedical 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 is suitable for any person involved in research, ranging from upper-level undergraduates to established faculty. Particular emphasis is given to the educational needs of graduate students and postdoctoral researchers.

LEARNING OBJECTIVES

- 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.

COURSE CONTENT

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

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IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Responsible Conduct of Research (RCR)

Social and Behavioural Responsible Conduct of Research

This course covers the core norms, principles, regulations, and rules governing the practice of biomedical 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 is suitable for any person involved in research, ranging from upper-level undergraduates to established faculty. Particular emphasis is given to the educational needs of graduate students and postdoctoral researchers.

LEARNING OBJECTIVES

- 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.

COURSE CONTENT

- Introduction to RCR
- Authorship
- Collaborative Research
- Conflicts of Interest
- Data Management
- Mentoring
- Peer Review
- Plagiarism
- Research Involving Human Subjects
- Research Misconduct
- Reproducibility of Research Results

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Responsible Conduct of Research (RCR)

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.

LEARNING OBJECTIVES

- Recognize various forms of financial conflicts of interest (FCOIs) in research.
- Identify the research team members who are subject to FCOI requirements.
- Identify the significant financial interests (SFIs) that investigators must disclose to their institutions.
- Recognize the ongoing obligations that investigators have relating to FCOIs.
- Describe how institutions collaborating on research projects identify, review, and manage conflicts of interest (COIs).
- Explain the circumstances under which an investigator's significant financial interest (SFI) or institutional financial interest could affect the objectivity of research.
- Recognize why institutions must develop management strategies to address FCOIs.

COURSE CONTENT

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

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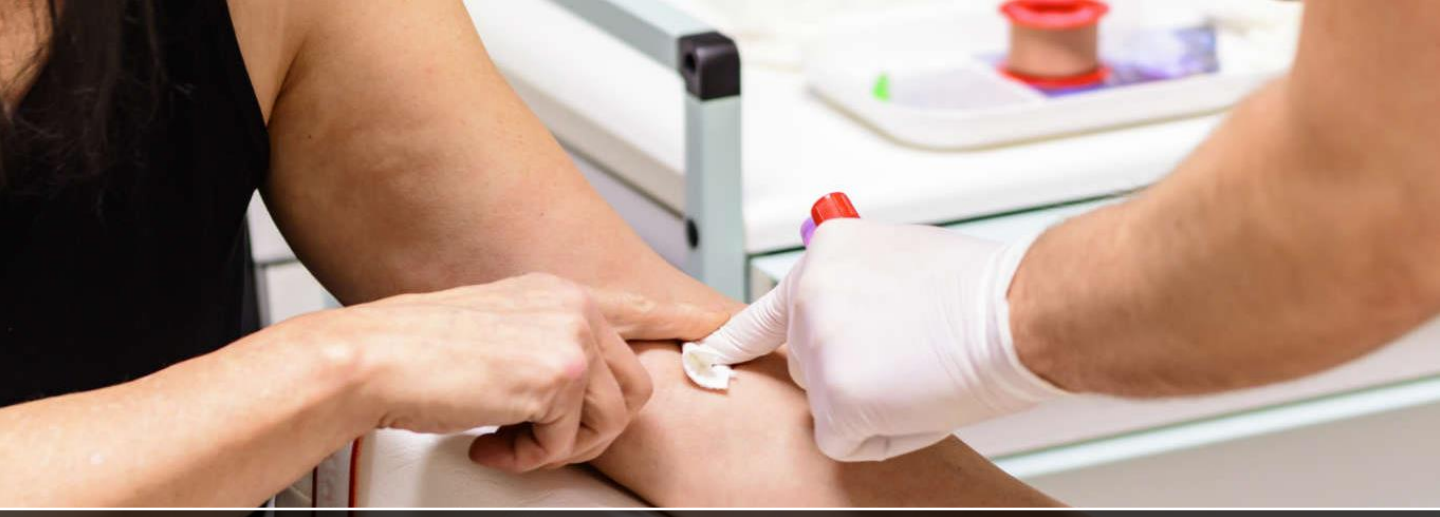

Human Subjects Research (HSR)

HSR for Biomedical Research

This course covers the core human subjects research topics for biomedical researchers.

ABOUT THIS COURSE

This course provides an introduction to the protection of human subjects in biomedical research. The HSR courses are suitable for all persons involved in research studies involving human subjects, or who have responsibilities for setting policies and procedures with respect to such research, including Institutional Review Boards (IRBs) and other members of organizational communities where research with human subjects occurs.

LEARNING OBJECTIVES

- Provides historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects.
- Provides foundational information about the human subject protection regulations and IRBs, including the role, authority, and composition of the IRB.
- Provides an introduction to potentially vulnerable populations or those requiring additional protections and/or considerations in research.

COURSE CONTENT

- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioural Research (SBR)
- Records-Based Research
- Genetic Research in Human Populations
- Research Involving Children
- FDA-Regulated Research
- Research and HIPAA Privacy Protections
- Vulnerable Subjects - Research Involving Workers/Employees
- Conflicts of Interest in Human Subjects Research
- Research Involving Prisoners

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Human Subjects Research (HSR)

HSR for Biomedical Data or Specimens Only Research

This course covers the training requirements for Investigators and staff involved primarily in research involving data or laboratory specimens with no direct contact with human subjects.

ABOUT THIS COURSE

This course provides an introduction to the protection of human subjects in biomedical research. The HSR courses are suitable for all persons involved in research studies involving human subjects, or who have responsibilities for setting policies and procedures with respect to such research, including Institutional Review Boards (IRBs) and other members of organizational communities where research with human subjects occurs.

LEARNING OBJECTIVES

- Provides a review of ethical, legal, and regulatory issues associated with genetic research.
- Discuss the issues surrounding the use of stored biological samples.
- Understand the risks associated with records-based research and how to minimize them.

COURSE CONTENT

- Populations in Research Requiring Additional Considerations and/or Protections
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Records-Based Research
- Genetic Research in Human Populations
- Conflicts of Interest in Human Subjects Research

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Human Subjects Research (HSR)

HSR for Social-Behavioural-Educational (SBE) Research

This course covers the core human subjects research topics for social-behavioural-educational researchers.

ABOUT THIS COURSE

The SBE Basic course provides an introduction to social-behavioural-educational research with a focus on the protection of human subjects. It offers historic and current information on regulatory and ethical issues important to the conduct of research involving human subjects.

LEARNING OBJECTIVES

- Distinguishes between privacy and confidentiality and identifies privacy risks associated with social behavioural study designs.
- Provides an overview of the types of education research and the regulations that apply to research in these settings.
- Discusses how ethical principles can be applied in the design, conduct, and review of Internet-based research.

COURSE CONTENT

- Populations in Research Requiring Additional Considerations and/or Protections
- History and Ethical Principles
- Defining Research with Human Subjects
- The Federal Regulations
- Assessing Risk
- Informed Consent
- Privacy and Confidentiality
- Research with Prisoners
- Research with Children
- Research in Public Schools
- International Research
- Internet-Based Research
- COI in Human Subjects Research
- Unanticipated Problems and Reporting
- Research and HIPAA Privacy Protections

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Human Subjects Research (HSR)

HSR for IRB Members

This course helps new Institutional Review Board (IRB) members understand their unique and critical role in the protection of human subjects.

ABOUT THIS COURSE

This course helps new Institutional Review Board (IRB) members understand their unique and critical role in the protection of human subjects. The module includes important concepts about the IRB. While the regulations that govern IRBs specify what the rules are, it is up to each institution to interpret and comply with them, through unique local policies and procedures. This course is appropriate for IRB or Ethics Committee members.

LEARNING OBJECTIVES

- Describe the structure and function of an IRB.
- Discuss the different types of reviews.
- Explain what you may review as part of the continuing review process.
- Summarize the impact of confidentiality on the work of IRBs.

COURSE CONTENT

- What Every New IRB Member Needs to Know
- Research with Persons who are Socially or Economically Disadvantaged (Optional)
- Consent and Subject Recruitment Challenges: Remuneration (Optional)
- Consent in the 21st Century (Optional)
- Ethical Issues in Public Health Research (Optional)
- Human Subjects Considerations and Big Data Research (Optional)
- Ethical and Appropriate Uses of Administrative Data for Research and Evaluation (Optional)
- Internet-Based Research (Optional)
- Hot Topics (Optional)
- Students in Research (Optional)

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Human Subjects Research (HSR)

Clinical Trial Agreement (CTA)

This course provides an overview of the CTA, the roles and responsibilities of the contract parties, and how the CTA fits into the research enterprise.

ABOUT THIS COURSE

CTAs are one of several key documents that govern the conduct of clinical trials. They serve as a legally binding contract between a sponsor, site, and researcher, and outline each party's responsibilities and obligations for the clinical trial. It is imperative that researchers and sites understand the importance of CTA development, negotiation, and execution, as effectiveness in these areas will increase efficiency, protect researchers/sites and subjects, and help advance research.

LEARNING OBJECTIVES

- Discusses the general purpose of a CTA, roles and responsibilities of parties to the CTA, and how the CTA fits into the research enterprise.
- Compares and contrasts clinical trials involving drugs, biologics, and devices from a CTA perspective.
- Discusses key roles of the researcher and site in managing the CTA.
- Provides an overview of the context behind certain CTA terms and sections, types of language used for CTA sections, and some key elements of each section.
- Addresses strategies and preparation for CTA and study budget negotiations.
- Identifies terminology and alternative wording options to ensure a fair and balanced CTA.

COURSE CONTENT

- Overview of the Clinical Trial Agreement
- Understanding the Terms of the Clinical Trial Agreement
- Role of the Researcher and Site in Managing the Clinical Trial Agreement
- Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

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Human Subjects Research (HSR)

Community-Engaged Research

This course introduces the ethical and practical considerations particular to the design, review, and conduct of CEnR.

ABOUT THIS COURSE

Community-Engaged Research (CEnR) refers to a cooperative approach to research that includes partnerships and collaboration among researchers and community organizations and agencies. Though partnerships and levels of collaboration can vary widely, the cooperative nature of CEnR promotes co-learning and recognizes the strength of community organizations and individuals.

LEARNING OBJECTIVES

- Identify movements and disciplines that contributed to the development of the CEnR approach.
- Explain how the principles of partnership and collaboration are important to the CEnR approach.
- Describe the main differences between a traditional research approach and the CEnR approach.
- Identify ethical and practical considerations unique to the design, review, and conduct of CEnR.
- Apply ethical risk-benefit assessments for CEnR.
- Describe the varying impacts that risks and benefits may have on individual research participants as well as on communities and groups.
- Identify strategies for training and educating community members on a research team.

COURSE CONTENT

- Introduction To Community-Engaged Research (CEnR)
- Introduction to Community-Based Participatory Research (CBPR)
- Ethical and Practical Considerations in Community-Engaged Research (CEnR)

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Human Subjects Research (HSR)

Consent

This course defines consent in human subjects research and covers how consent should be managed in the informed consent process.

ABOUT THIS COURSE

This course content is for those involved in obtaining and recording informed consent (researchers and study coordinators), those reviewing informed consent processes and documents (IRB members and administrators), and those designing or conducting research projects where informed consent will be obtained or waived.

LEARNING OBJECTIVES

- Describe different types of consent in research.
- Identify key regulatory requirements regarding remuneration to research subjects.
- Identify ways of disclosing remuneration plans in consent and advertising materials.
- List the technology tools that may be used in the recruitment and consent process.
- Discuss confidentiality issues with the use of technology in the consent process.

COURSE CONTENT

- Consent and Subject Recruitment Challenges: Remuneration
- Consent Tools Used by Researchers
- Consent in the 21st Century
- Consent and Biobanks and Associated Databases
- Consent and Subject Recruitment Challenges: Therapeutic Misconception
- Consent with Subjects Who Do Not Speak English
- Consent and Cultural Competence
- Informed Consent and Incidental Findings in Research with Human Subjects

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Human Subjects Research (HSR)

Disaster and Conflict Research

This course covers the practical challenges and strategies for human subjects research in natural and man-made disasters (including conflicts)

ABOUT THIS COURSE

Contemporary disasters present significant practical and ethical challenges for both medical responders and researchers because of the diversity and complexity of today's disasters, austere environments in which many disasters occur, and presence of conflicts in the affected regions, before, during, and after the disaster. This course discusses practical challenges and strategies for human subjects research in natural and man-made disasters (including conflicts).

LEARNING OBJECTIVES

- Discuss contemporary disaster management terminology and the unique features of disasters and conflict situations that affect research initiatives.
- Differentiate between disaster responses in low resource settings versus high income countries.
- Identify the frameworks for disaster management utilized by public health and medical providers to enhance communication between research teams and disaster responders.
- Identify the public health and medical concerns in disasters that affect disaster research initiatives.
- Identifies the research tools and methods in disaster management.
- Provides guidelines for conducting disaster and conflict research.

COURSE CONTENT

- Disaster and Conflict Research, Part 1: PI Responsibilities
- Disaster and Conflict Research, Part 2: Best Practices and Recommendations

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NEW

Human Subjects Research (HSR)

Phase I Research

This course aims to increase awareness of phase I research as it relates to regulatory requirements, IRB review, and safeguards for protecting human research subjects.

ABOUT THIS COURSE

Phase I research provides the foundation and start of the drug development process. The data collected from these initial studies in humans have a large impact on drug development and ultimately to the safety of the human subjects who receive the drugs in the future. All individuals involved in phase I research must understand its importance, as the stage facilitates testing and development of the new drug's safety profile.

These modules are intended to be taken sequentially by all principal investigators and individuals engaged or involved in the protection of human subjects in phase I research, including but not limited to: Investigators, IRB members, Institutional Officials, IRB staff, research coordinators, research administrators, students, sponsors, and CROs.

LEARNING OBJECTIVES

- Define phase I research as it relates to non-clinical and other phases of research.
- Identify routine study designs used to develop the initial safety profile and achieve study objectives in phase I research.
- Describe changes in the phase I research landscape.
- Identifies ways in which researchers and staff involved in phase I research can apply the necessary safeguards to protect subjects involved in phase I research.

COURSE CONTENT

- Understanding Phase I Research
- Protecting Phase I Subjects

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Human Subjects Research (HSR)

Human Subjects Research (HSR) Involving Specific Population

This course provides an introduction to potentially vulnerable populations or those requiring additional protections and/or considerations in research.

ABOUT THIS COURSE

This course provides an introduction to potentially vulnerable populations or those requiring additional protections and/or considerations in research. It describes different sources of vulnerability and distinguishes between populations in research who are specifically protected in the federal regulations and those who are not. The module also discusses the impact on autonomy, beneficence, and justice that may arise due to research on or with vulnerable individuals or groups.

LEARNING OBJECTIVES

- Provides training regarding the conduct of research with individuals who are socially or economically disadvantaged.
- Provides insight regarding risks and challenges of conducting research with individuals who are engaged in illegal activities or who have undocumented status.
- Discusses the issues related to students as researchers and subjects.

COURSE CONTENT

- Research with Older Adults
- Research with Persons who are Socially or Economically Disadvantaged
- Gender and Sexuality Diversity
- Research with Critically Ill Subjects
- Research with Decisionally Impaired Subjects
- Illegal Activities or Undocumented Status in Human Research
- Research with Subjects with Physical Disabilities & Impairments
- Research Involving Subjects at the End-of-Life
- Research Involving Children
- Vulnerable Subjects - Research Involving Workers/Employees
- Students in Research
- Research Involving Pregnant Women, Foetuses, and Neonates

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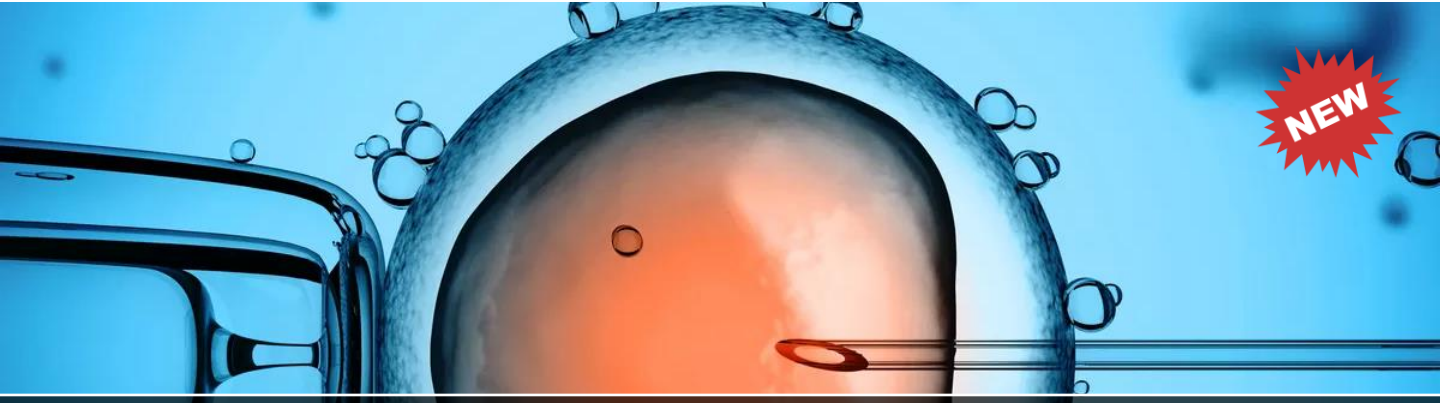

Human Subjects Research (HSR)

Human Subjects Research (HSR) Involving Stem Cells

This course introduces the learner to the nature of both adult and embryonic stem cells and provides a framework for IRB institutional review of stem cell research.

ABOUT THIS COURSE

This course introduces the learner to the nature and characteristics of both adult and embryonic stem cells. Learners are provided with a review of the requirements of the federal regulations associated with stem cell research and the role of both state and local requirements.

LEARNING OBJECTIVES

- Introduces the nature and characteristics of both adult and embryonic stem cells.
- Discusses the contentious historical and ethical issues surrounding stem cell research and the clinical application of stem cells.
- Provides a framework for institutional review of stem cell research
- Provides a detailed overview of the recommendations of the US NAS, ISSCR, and NIH Guidelines as well as information related to the procurement, banking, and use of human stem cell lines.

COURSE CONTENT

- Stem Cell Research Oversight
- Genetic Research in Human Populations
- Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
- Populations in Research Requiring Additional Considerations and/or Protections
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Records-Based Research
- Research Involving Children
- Conflicts of Interest in Human Subjects Research
- Research Involving Pregnant Women, Foetuses, and Neonates

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Human Subjects Research (HSR)

Human Subjects Research (HSR) for Public Health Researchers

This course introduces the learner to the nature of both adult and embryonic stem cells and provides a framework for IRB institutional review of stem cell research.

ABOUT THIS COURSE

While public health research is subject to the same rigorous scientific and ethical standards as other human subjects research, both the unique features and legislative mandates of public health require special treatment. The conduct of research activities is a major mission of public health professionals, as many of the usual functions performed in routine practice involve surveillance, assessment, or process improvement. It is also important to understand the overlap between public health practice and research.

LEARNING OBJECTIVES

- Describe the roles, responsibilities, and activities of public health systems, as well as the structures and functions.
- Understand and compare characteristics of public health systems.
- Identify essential public health services and their interrelationships with core public health functions.

COURSE CONTENT

- Introduction to Public Health Research
- Public Health Research and Public Health Practice
- Informed Consent and Confidentiality in Public Health Research
- Ethical Issues in Public Health Research
- Populations in Research Requiring Additional Considerations and/or Protections
- History and Ethics of Human Subjects Research
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioral Research (SBR) for Biomedical Researchers
- Records-Based Research
- Conflicts of Interest in Human Subjects Research

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Conducting Research Involving Animals

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

ABOUT THIS COURSE

The course provides basic information regarding the regulations for protection of animal subjects used in research, teaching, and testing. It also describes the sources and applicability of regulations governing animals in these uses.

LEARNING OBJECTIVES

- 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.
- Demonstrate familiarity with the basic principles of the conduct of experimental surgery.
- Specify humane endpoints and appropriate euthanasia.

COURSE CONTENT

- Working with the IACUC: Introduction
- About the IACUC
- Federal Laws, Policies, and Guidelines
- Planning Research and Completing the Protocol Form
- Procedures: Surgery, Antibody Production, and Blood Collection
- Personnel and Their Welfare
- Special Animal Welfare Considerations
- Making Changes to an Approved Animal Use Protocol
- Reporting Animal Use Concerns

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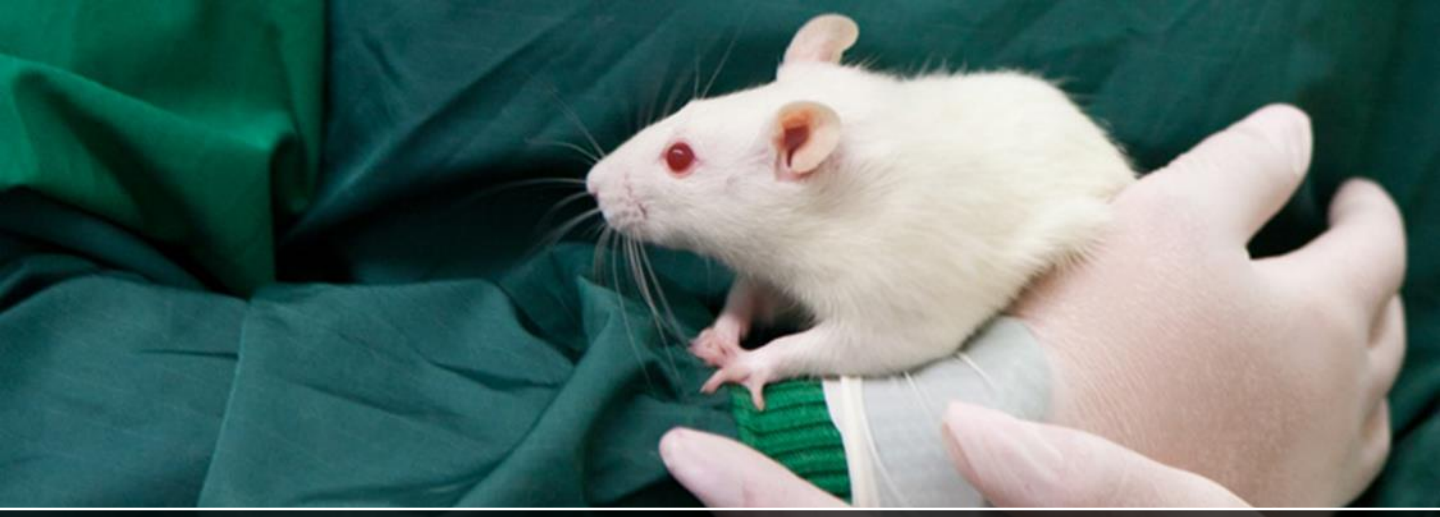

Animal Care and Use (ACU)

Essentials for IACUC Members

This course offers in-depth training for IACUC members.

ABOUT THIS COURSE

This course provides an in-depth look at Institutional Animal Care and Use Committee (IACUC) responsibilities, authority, and membership, as well as the IACUC's relationship with the Chief Executive Officer (CEO) and Institutional Official (IO).

LEARNING OBJECTIVES

- Identify how an animal activity may be suspended.
- Discuss the process and possible outcomes of full committee review of animal use protocols.
- Compare the relationship between animal welfare regulations and the ethical treatment of animals, in contrast to the ethical treatment of human subjects involved in research.

COURSE CONTENT

- Essentials for IACUC Members: Introduction
- Federal Laws, Policies, and Guidelines
- IACUC and IACUC Member Responsibilities
- IACUC Membership Requirements
- Quorum, Alternate Members, and Telecommunications
- The IACUC, CEO, and IO
- Protocol Review
- Suspending Animal Activities
- Types of IACUC Review: Initial, Annual, Triennial
- Documenting IACUC Actions
- Semiannual Evaluations – An Overview
- Facility Inspections and Program Review
- Identifying, Documenting, and Correcting Deficiencies

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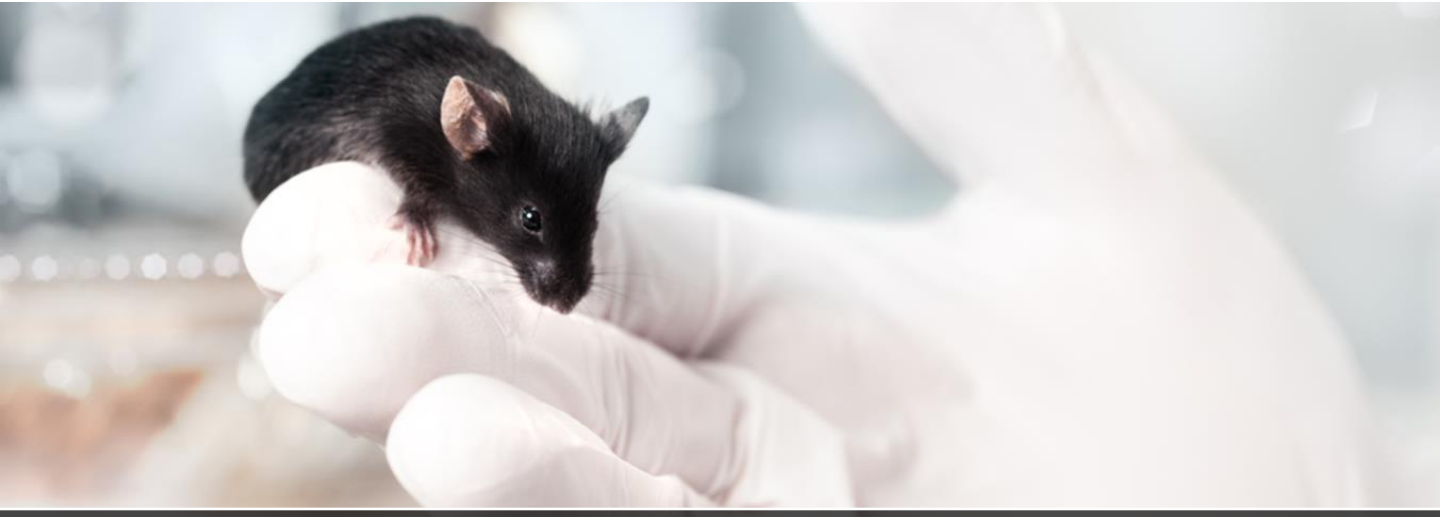

Animal Care and Use (ACU)

IACUC Community Member

This course provides a brief history of the Animal Welfare Regulations (AWR) and formation of the IACUC.

ABOUT THIS COURSE

CITI Program's IACUC Community Member course is designed for new Institutional Animal Care and Use Committee (IACUC) community members (non-affiliated and/or non-scientific members), but can be used by anyone involved with animal research, testing, or teaching. It provides the basic tools, sense of reality, and approach one needs to become a well-informed IACUC community member. The course also offers an opportunity to learn various aspects of the IACUC process appropriate to specific kinds of protocols.

LEARNING OBJECTIVES

- Identify the agencies that regulate the use of animals in research, testing, and teaching, including what species they regulate.
- Identify which other documents guide institutional policies related to animal husbandry, housing and caging environments, veterinary care, and physical plant.
- Summarize the constitution, basic responsibilities, and procedures of IACUCs.
- Discuss the process and possible outcomes of IACUC review of animal use protocols.
- Discuss continuing review of protocols at one and three year intervals.
- Outline the major requirements and goals of semiannual evaluation.
- Evaluate the relationship between the Animal Welfare Regulations (AWR) and ethical treatment of animals.

COURSE CONTENT

- Ethics, Regulations, and the IACUC
- IACUC Basics
- Full-committee Meetings and DMR
- Other Responsibilities of IACUC Members
- Additional Tips for Community Members

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress

This course offers training on post-procedure care of mice and rats in research.

ABOUT THIS COURSE

This course offers information on how to minimize pain and distress in mice and rats during and after experimental procedures. It discusses detection and monitoring signs of pain in animals; the use of animal appearance and behaviour, physical condition, and body weight in the monitoring process; the role of body temperature and fluid, and electrolyte balance in animal welfare; and the alleviation of pain and distress in the post-procedure animal.

LEARNING OBJECTIVES

- Explain the role of humane care in minimizing non-experimental variations
- Explain the principles of detecting pain and distress in rats and mice
- Discuss the nature of the physical exam for clinical condition
- List the parameters of the physical exam, discuss how to assess them and how to treat abnormalities

COURSE CONTENT

- Introduction to Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
- Investigator Responsibility
- Minimizing Sources of Nonexperimental Variation
- Systematically Monitoring for Pain and Distress
- Detecting Clinical Signs of Pain and Distress
- Appearance and Behaviour
- Physical Exam for Clinical Condition
- Body Weight
- Fluid and Electrolyte Balance
- Body Temperature
- Tumours
- Alleviation of Pain and Distress
- Documentation of Post-Procedure Care

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Wildlife Research

This course provides training for persons involved in wildlife research.

ABOUT THIS COURSE

This course describes the types of field studies, methods of animal capture, principles and methods of restraint, animal marking, animal transportation and housing, maintenance of wildlife in captivity, translocation and release, animal surgery, blood sample collection, recognition and management of pain, and euthanasia.

This course will not provide detailed information on specific methods or procedures. Other courses offering in-depth information and hands-on instruction might be available through your institutional staff or other resources.

LEARNING OBJECTIVES

- Determine when animal welfare regulations and policies apply to wildlife research.
- Identify the occupational safety and health concerns that arise in wildlife research and the need to evaluate the nature and extent of the risk to determine appropriate precaution.
- Describe the two main types of wildlife research.
- Discuss field-appropriate methods for alleviating pain and suffering, achieving aseptic conditions, and ensuring that proper surgical techniques are used.
- Discuss field-appropriate methods of euthanasia.

COURSE CONTENT

- Introduction to Wildlife Research Course
- Oversight, Compliance, and Training
- Permits, Pain and Distress Categories, Transportation, and Housing
- Conducting Field Research and Teaching Studies
- Research Procedures, Recognizing and Managing Pain, and Release

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Post-Approval Monitoring (PAM)

This course offers training on post-approval monitoring.

ABOUT THIS COURSE

There are a variety of formal and informal ways in which PAM can be incorporated into an animal care and use program, including audits, laboratory (lab) surveys, Institutional Animal Care and Use Committee (IACUC) protocol reviews, facility inspections, adverse event reporting, veterinary rounds, animal care staff reports to facility managers, casual lab visits, veterinary follow-up on healthcare reports, and consultations.

This module deals with PAM in the laboratory research setting as typically found in academic institutions and industry.

LEARNING OBJECTIVES

- Describe the regulations and guidelines pertaining to PAM programs.
- Describe what actions constitute PAM, and those that do not.
- Discuss what to do and what not to do when conducting a PAM visit.

COURSE CONTENT

- Post-Approval Monitoring (PAM)

CITI PROGRAM
IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Working with Mice in Research

This course provides training on working with mice in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with mice in research settings including the regulatory mandates and biological features of mice.

If you are responsible for handling mice or if you must write an animal use protocol, this course will be useful by providing you with:

- Information on key regulatory issues.
- Guidance on searches for alternatives in the care and use of animals.
- Highlights of unique biological features of these animals.
- Overviews of acceptable basic methodologies.
- Requirements for supportive care procedures.

COURSE CONTENT

- Introduction to Working with Mice in Research Settings
- Research Mandates and Occupational Health Issues
- Alternatives Search, Humane Standards, Housing, Source, and Acclimation and Quarantine
- Detecting Pain and Distress, Genetics, and Biological Features
- Injections, Blood Collection, and Antibody Production
- Surgery, Supportive Care and Monitoring, Euthanasia, and References

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Working with Rats in Research

This course provides training on working with rats in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with rats in research settings including the regulatory mandates and biological features of rats.

If you are responsible for handling rats or if you must write an animal use protocol, this course will be useful by providing you with:

- Summaries of key regulatory issues.
- Guidance on searches for alternatives in the care and use of animals.
- Highlights of unique biological features of these animals.
- Overviews of acceptable basic methodologies.
- Requirements for supportive care procedures.

COURSE CONTENT

- Introduction to Working with Rats in Research Settings
- Research Mandates and Occupational Health Issues
- Alternatives Searches, Humane Standards, Housing, and Acclimation and Quarantine
- Detecting Pain and Distress, Genetics, and Biological Features
- Injections, Blood Collection, Antibody Production, and Pain Relief
- Surgery, Supportive Care and Monitoring, Euthanasia, and References

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Working with Rabbits in Research

This course provides training on working with rabbits in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with rabbits in research settings including the regulatory mandates and biological features of rabbits.

If you are responsible for handling rats or if you must write an animal use protocol, this course will be useful by providing you with:

- Information on key regulatory issues.
- Guidance on searches for alternatives in the care and use of animals.
- Highlights of unique biological features of these animals.
- Overviews of acceptable basic methodologies.
- Requirements for supportive care procedures.

COURSE CONTENT

- Introduction to Working with Rabbits in Research Settings
- Research Mandates and Occupational Health Issues
- Alternatives Searches, Humane Standards, Housing, and Acclimation and Quarantine
- Detecting Pain and Distress, Genetics, and Biological Features
- Injections, Blood Collection, Antibody Production, and Pain Relief
- Surgery, Supportive Care and Monitoring, Euthanasia, and References

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IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Working with Guinea Pigs in Research

This course provides training on working with guinea pigs in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with guinea pigs in research settings including the regulatory mandates and biological features of guinea pigs.

If you are responsible for handling rats or if you must write an animal use protocol, this course will be useful by providing you with:

- Information on key regulatory issues.
- Guidance on searches for alternatives in the care and use of animals.
- Highlights of unique biological features of these animals.
- Overviews of acceptable basic methodologies.
- Requirements for supportive care procedures.

COURSE CONTENT

- Introduction to Working with Guinea Pigs in Research Settings
- Taxonomy, Research Mandates, and Occupational Health Issues
- Alternatives Search, Humane Standards, Acclimation and Quarantine, Housing, and Detection of Pain and Distress
- Genetics, Biology, Injections and Blood Collection, Antibody Production, and Pain Relief
- Surgery, Supportive Care and Monitoring, Euthanasia, and References

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Animal Care and Use (ACU)

Working with Hamsters in Research

This course provides training on working with hamsters in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with hamsters in research settings including the regulatory mandates and biological features of hamsters.

If you are responsible for handling rats or if you must write an animal use protocol, this course will be useful by providing you with:

- Information on key regulatory issues.
- Guidance on searches for alternatives in the care and use of animals.
- Highlights of unique biological features of these animals.
- Overviews of acceptable basic methodologies.
- Requirements for supportive care procedures.

COURSE CONTENT

- Introduction to Working with Hamsters in Research Settings
- Research Mandates and Occupational Health Issues
- Alternatives Search, Humane Standards, Housing, Acclimation and Quarantine, Detecting Pain and Distress
- Species/Strains (ID 1992)
- Surgery, Supportive Care and Monitoring, Euthanasia, and References

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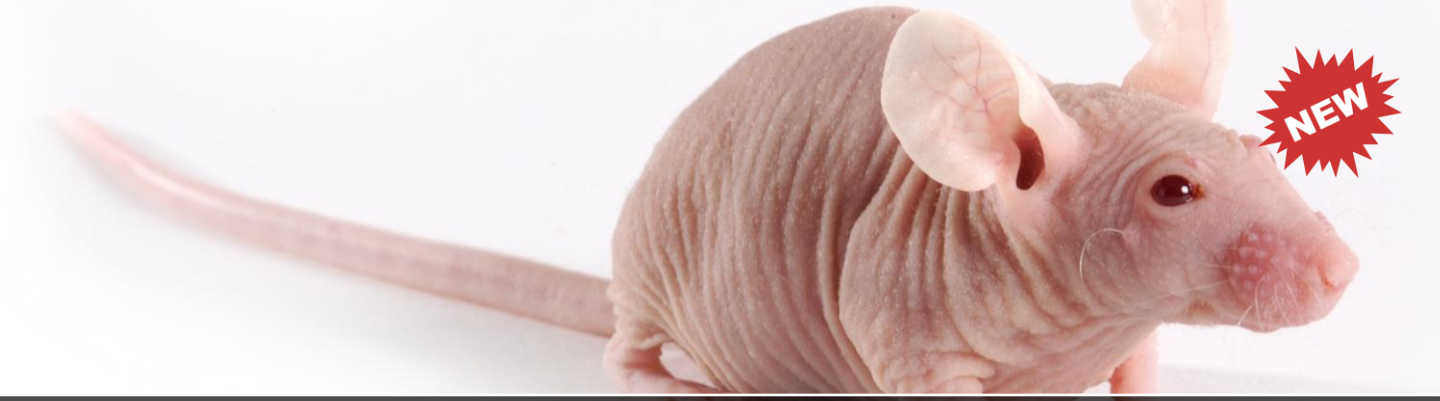

Animal Care and Use (ACU)

Working with Genetically Modified Mice in Research Settings

This course provides training on working with genetically modified mice in research settings.

ABOUT THIS COURSE

This course offers an introduction to working with genetically modified mice in research settings, including basic concepts and history, nomenclature, genetic engineering, breeding and maintenance, and animal welfare and regulations.

This course will be useful by providing you with:

- Basic concepts and history of working with genetically modified mice.
- Information on standard nomenclature for gene symbols and gene names, how to use the Mouse Genome Informatics (MGI) resource, the usefulness and standardization of laboratory codes, differences in strains, and common inbred parental strains and substrains.
- Overview of genetic engineering for generating genetically modified mouse models
- Animal welfare and regulatory issues and guidelines associated with the production of genetically modified mice

COURSE CONTENT

- Basic Concepts and History
- Nomenclature
- Genetic Engineering
- Breeding and Maintenance
- Animal Welfare and Regulations

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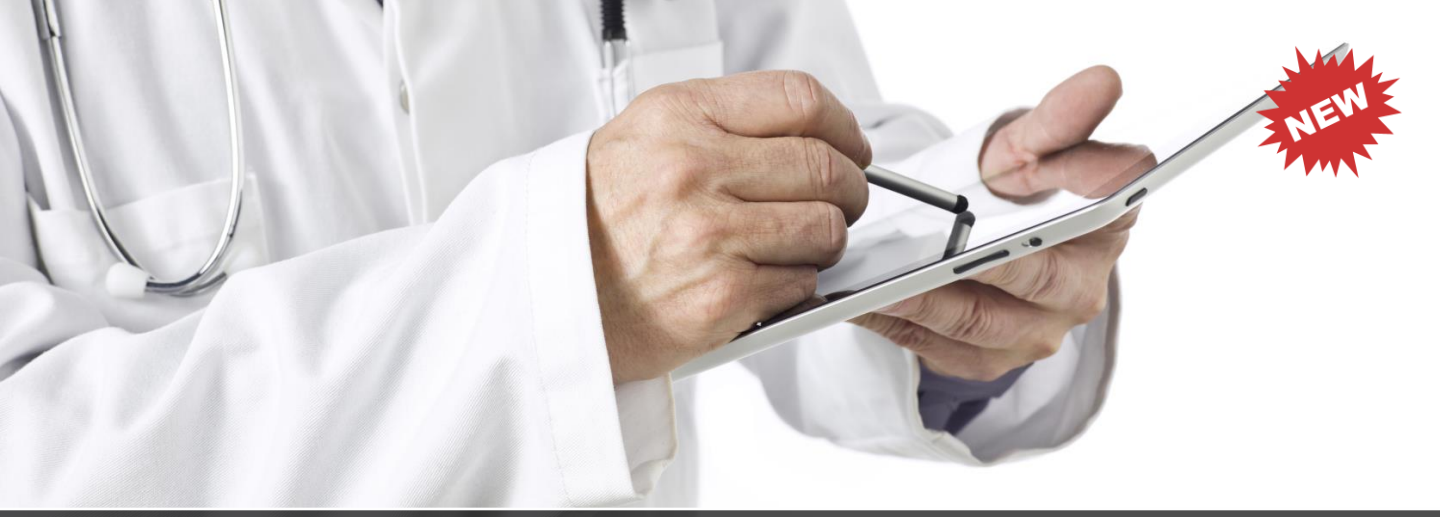

Information Privacy & Security (IPS)

Health Privacy

This course is intended to cover the core elements of the federal Health Insurance Portability and Accountability Act (HIPAA) requirements.

ABOUT THIS COURSE

The foundation concepts of this course are covered in the Basics of Health Privacy module, which provides information on the core elements of the federal Health Insurance Portability and Accountability Act (HIPAA) requirements. Additional content is meant to supplement this foundation by focusing on healthcare roles and types of activities, since HIPAA's requirements are largely conditioned by the purposes behind the collection, use, or disclosure of health information.

LEARNING OBJECTIVES

- Provides general information about health privacy, applicable to all members of the healthcare workforce.
- Discusses how HIPAA applies to providing treatment services, engaged in fundraising activities, or engaged in marketing activities.
- Discusses data protection requirements for human subjects research that creates, obtains, uses, or discloses health data
- Discusses how HIPAA applies to persons engaged in educational activities, whether as students or instructors.

COURSE CONTENT

- Health Privacy Issues for Students and Instructors
- Health Privacy Issues for Fundraisers
- Health Privacy Issues for Marketers
- Basics of Health Privacy
- Health Privacy Issues for Clinicians
- Basics of Information Security
- Health Privacy Issues for Researchers

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Information Privacy & Security (IPS)

Information Security

This course provides information on basic techniques for data and device security, including email and mobile devices.

ABOUT THIS COURSE

This course provides information on basic techniques for data and device security, including email and mobile devices.

LEARNING OBJECTIVES

- Describe the basic security issues with various types of non-electric information, information use, and information "devices."
- Provides practices for safer use of passwords, which are the most common method of authenticating one's identity in electronic contexts.
- Discusses practices to protect non-portable computers, with application to portable devices as well.
- Addresses the risks associated with the use of portable computing devices and presents to learners ways of implementing "best practices" for safer use of portable devices.
- Provides an in-depth discussion on safe practices for users of social networking sites and applications.
- Provides standard recommendations for good identity practices.
- Discusses the safe use of websites and related applications.
- Discusses the special security needs of off-site work and workers.

COURSE CONTENT

- Basics of Information Security
- Protecting Your Computer
- Protecting Your Portable Devices
- Protecting Your Identity
- Safer Emailing and Messaging-
- Safer Web Surfing
- Security for Work/Workers Off-Site
- Picking and Protecting Passwords
- Safer Social Networking

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Information Privacy & Security (IPS)

Family Educational Rights and Privacy Act (FERPA)

This course covers the core requirements of the federal Family Educational Rights and Privacy Act (FERPA).

ABOUT THIS COURSE

The Family Educational Rights and Privacy Act (FERPA) protects the privacy of students by giving them (and their parents if they are minors) access to their educational records and control over how this information is disclosed to third parties.

Professionals who work in education should know the law's core aspects to ensure compliance with the regulations.

LEARNING OBJECTIVES

- Discusses FERPA as it applies to instructors (anyone in a teaching role from elementary school teachers to university professors) that handle and manage student data and information.
- Informs students about FERPA and the rights and responsibilities the law affords them.
- Discusses student rights as they relate to accessing and amending educational records, different types of student information and their level of protection.
- Identifies the level of risk in using different types of student data for research, how to employ safe methods in the collection and analysis of student data.
- Discusses issues around student data and privacy from the perspective of IRBs.
- Discusses administrator roles and responsibilities on the use and disclosure of student records and data.

COURSE CONTENT

- Basics of Information Security
- FERPA: An Introduction
- FERPA for Instructors
- FERPA for Students
- FERPA for Researchers
- FERPA for Institutional Review Boards (IRBs)
- FERPA for Educational Administrators

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Good Clinical Practice (GCP)

Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

This course is suitable for individuals proposing to conduct clinical trials of drugs, biologics, and devices primarily in the U.S. and/or who would prefer a more U.S. FDA-centric curriculum.

ABOUT THIS COURSE

The GCP U.S. FDA Basic course covers Good Clinical Practice (GCP) and U.S. Food and Drug Administration (FDA) essential topics for clinical trials with investigational drugs, biologics, and/or medical devices. It is intended for research personnel involved in drug, biologic, or device studies and who would benefit from FDA-focused training.

The course describes the role of industry sponsors in the conduct of clinical trials under an investigational new drug (IND) application according to FDA regulations. Provides an overview of definitions, procedures, and timelines associated with the development of a new drug. Also covers electronic records and signatures pursuant to 21 CFR Part 11 and ClinicalTrials.gov requirements pursuant to 42 CFR Part 11.

LEARNING OBJECTIVES

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

- Evaluate federal regulations for clinical research and drug development.
- Determine the role of the International Council for Harmonisation.
- Recognize the role of international standards on clinical research.
- Identify clinical researcher responsibilities.

TOPICS INCLUDE

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

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Good Clinical Practice (GCP)

Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

This course is suitable for individuals proposing to conduct clinical trials of drugs and biologics in the U.S. and internationally and/or who would prefer a more ICH-centric curriculum.

ABOUT THIS COURSE

The GCP ICH Basic 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.

It is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training, or for researchers involved in studies where compliance with ICH is required (for example, most industry-funded studies). It should be noted, however, that when appropriate, references to U.S. Food and Drug Administration (FDA) regulations and guidance are included.

LEARNING OBJECTIVES

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

- Evaluate federal regulations for clinical research and drug development.
- Determine the role of the International Council for Harmonisation.
- Recognize the role of international standards on clinical research.
- Identify clinical researcher responsibilities.

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

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Good Clinical Practice (GCP)

Clinical Investigations of Devices

This course provides training for research personnel involved in clinical investigations of devices.

ABOUT THIS COURSE

The GCP Device Basic course is intended for research personnel involved in investigations of devices. It includes FDA regulations and guidance as well as International Organization for Standardization Guidelines ISO 14155:2011.

LEARNING OBJECTIVES

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

- Evaluate federal regulations for clinical research and device development.
- Recognize the role of international standards on clinical research.
- Identify clinical researcher and sponsor responsibilities.
- Discuss the reporting requirements and oversight of clinical investigations of devices.

TOPICS INCLUDE

- Overview of U.S. FDA Regulations for Investigational Devices
- Investigator Obligations in FDA-Regulated Clinical Investigations of Devices
- Conducting Investigator-Initiated Clinical Investigations of Devices
- Managing Investigational Devices According to GCP Requirements
- Informed Consent in Clinical Investigations of Devices
- Monitoring Clinical Investigations of Devices
- Audits and Inspections of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Completing the CITI Program's GCP Course for Clinical Investigations of Devices

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

Good Clinical Practice (GCP)

Social and Behavioural Research Best Practices for Clinical Research

This course is suitable for social and behavioural investigators and staff who must be trained in GCP.

ABOUT THIS COURSE

The GCP – Social and Behavioural Research Best Practices for Clinical Research course introduces GCP principles and discusses how they apply to clinical trials using behavioural interventions and social science research. This course is presented in a dynamic, nine-module format with narration, interactive features, and downloadable resources.

It discusses the elements of a social and behavioural research Institutional Review Board (IRB) protocol and standard operating procedures (SOPs); Introduces the concept of treatment fidelity and discusses strategies to minimize protocol deviations; Presents a number of best practices for recruiting participants and keeping them enrolled and engaged in the study; and provides strategies to protect participant privacy and confidentiality.

COURSE CONTENT

- Introduction
- Research Protocol
- Recruitment and Retention
- Informed Consent Communication
- Privacy and Confidentiality
- Participant Safety and Adverse Event Reporting
- Quality Control and Assurance
- Research Misconduct
- Conclusion

CITI PROGRAM

IMU IRDI INSTITUTE FOR RESEARCH, DEVELOPMENT & INNOVATION

FAQs

What is IMU-CITI Program?

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.

What are the advantages of CITI Program?

CITI Program is a nationally and internationally recognized expert in research ethics, compliance, and professional education. The program is trusted by top organizations around the world and the certificate is recognized by various institutions globally.

Why does IMU recommend research students to sign up for the CITI Program training?

By completing the CITI Program training, we are conforming to best practices concerning the ethical and responsible conduct of research.

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.

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 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%.

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.

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.

Is the CITI training compulsory to all student researchers?

No. Student researchers are not required by the University to complete CITI Training. However, Principle Investigators who are mentoring student researchers may find it helpful for students to complete the training as to conform to the best practices concerning the ethical and responsible conduct of research.

FAQs

How much does it cost?

CITI Program is designed to be a cost-effective and easy to manage training solution for individual learner. Learners (i.e IMU students or alumni) who are affiliated with IMU can take selected CITI Program courses for a minimal one-time subscription fee.

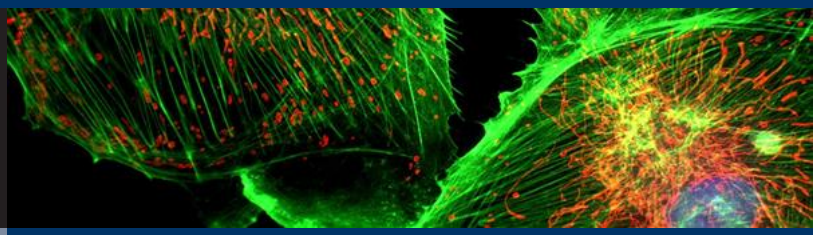
Those who are not affiliated with IMU or need additional content not offered through IMU can purchase courses as an independent learner. Course fees for independent learners start at $50 USD.

What happens after I complete a course?

Once all required course content is complete including finishing all quizzes with a passing score, you will be able to download a Completion Report and a Certificate of Completion. You will also be able to access a unique online link for that course that you can share when needed.

IRDI Collaborative Institutional Training Program

Research Ethics and Compliance Training



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