The CITI Program’s Mission: To promote the public’s trust in the research enterprise by providing high quality, web based, research ethics educational materials to enhance the integrity and professionalism of investigators and staff conducting research.

Not receiving updates from CITI program? E-mail citiadmin@med.miami.edu to add or modify subscription settings

THE CITI PROGRAM’S NEWEST MEMBERS

Joining the more than 1,500 institutions and organizations committed to research ethics, the CITI Program is proud to welcome these new facilities:

- Texas A&M University
- Kaiser Foundation Research Institute
- Florida State University College of Medicine
- Medco Health Solutions
- American Cancer Society
- Advanced Research Institute
- Amway Corporation
- Children’s Hospital Central California
- National Taiwan University
- National Council of State Boards of Nursing (NCSBN)
- University of Puerto Rico at Cayey
- Rhode Island School of Design

To view the complete list of all participating institutions, please visit www.citiprogram.org/institutions

THE CITI PROGRAM: A GLOBAL PRESENCE

Did you know that 70% of the world map has visited www.citiprogram.org?

On average, we welcome visitors from more than 135 countries every week! The CITI Program has affiliated Centers of Excellence in many countries, including Canada, India, Japan, Korea, Peru, Ukraine, Colombia and Taiwan. Each affiliate’s site includes content of interest to the country or region it represents and access to the full collection of CITI materials.

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ABOUT CITI

The Collaborative Institutional Training Initiative (CITI Program) is a web-based training platform that was founded in 2000 as a collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center. Today, the CITI Program is used by more than 1500 institutions and organizations worldwide with 2.8 million people completing courses to date.

CITI COURSES

We can help you design a customized curriculum, specifically tailored to your institution’s needs.

HUMAN SUBJECTS RESEARCH
- Biomedical Focus
- Social and Behavioral Focus
- Refresher Courses

GOOD CLINICAL PRACTICE
- U.S. FDA Focus
- Clinical Trials Involving Drugs (ICH Focus)
- Clinical Trials Involving Devices

RESPONSIBLE CONDUCT OF RESEARCH
- Research Misconduct
- Data Acquisition, Management, Sharing and Ownership
- Publication Practices and Responsible Authorship
- Peer Review
- Mentor and Trainee Responsibilities
- Conflicts of Interest and Commitment
- Collaborative Research
- Animal Welfare
- RCR for Engineers Course
- RCR for Administrators Course

HEALTH INFORMATION PRIVACY AND SECURITY (HIPAA)

ANIMAL CARE & USE (MULTIPLE SPECIES)
- Laboratory Animal Research Courses for Investigators and IACUC Members
- Animal Model Specific Courses

BIO-SAFETY AND BIO-SECURITY (NEW)

U.S. EXPORT CONTROL REGULATIONS (NEW)

Ready to take a course demo? Call us at (305) 243-7970 or e-mail us at citiadmin@med.miami.edu

Contact CITI! We are available to answer questions or provide help desk support. Call us at (305) 243-7970 or e-mail us at citiadmin@med.miami.edu
NEW GCP COURSES COVER ICH-FOCUSED DRUG AND DEVICE TRIALS

As prescribed by international standards and requirements, a basic understanding of Good Clinical Practice is a prerequisite for anyone carrying out, or involved in, clinical research and trials. The CITI Program has added two new courses to meet these needs.

**Good Clinical Practice Course (US FDA Focus)**

This course is a 13-module program that discusses good clinical practice as it relates to clinical trials of both drugs/biologics as well as devices. The discussion is focused on the U.S. Food and Drug Administration (U.S. FDA) regulatory requirements, but does contain information related to International Conference on Harmonisation (ICH) guidelines, which were adopted to aid in compliance with regulatory requirements of international government agencies. Modules include Overview of New Drug Development, FDA Regulated Research and ICH for Investigators, Investigator Obligations in FDA-Regulated Clinical Research and Informed Consent.

**Good Clinical Practice Course for Clinical Trials Involving Drugs (ICH Focus)**

This course is a 13-module program that provides information on good clinical practice as it relates to clinical trials involving drugs and biologics. The information is presented in the context of International Conference on Harmonisation (ICH) guidelines, but also includes relevant U.S. FDA regulations and guidance. Modules include ICH overview; Comparison between ICH GCP E6 and U.S. FDA Regulations, Audits and Inspections in Clinical Trials, Conducting Investigator-initiated Studies according to FDA Regulations and Good Clinical Practices and Informed Consent. This course may be most appropriate for organizations or individuals who desire a more international focused GCP curriculum.

**Good Clinical Practice Course for Clinical Trials Involving Devices**

This course is a 10-module program that provides information on good clinical practice for clinical trials involving devices. Modules include Managing Investigational Devices According to GCP Requirements, Audits and Inspections in Clinical Trials, Conducting Investigator-initiated Studies according to FDA Regulations and Good Clinical Practices, Monitoring of Clinical Trials by Industry Sponsors and Informed Consent. This course may be most appropriate for organizations or individuals who desire a device-focused program.

**Does Your Institution Comply with Export Control Regulations?**

Since the terrorist attacks on 9/11/2001, heightened security measures in the United States have become a way of life. Compliance with the U.S. Export Control Regulations has become increasingly important at universities and colleges in the U.S. Specific training for investigators and staff in U.S. Export Control Regulations is essential to ensure that all individuals conducting research with “dual use” materials—agents or devices—are in compliance with all federal laws. The consequences of non-compliance can be fines to your university or organization of up to $1 million and the criminal prosecution of offending investigators.

The CITI Program has developed a new four-module course on US Export Control Regulations.

1. An overview of U.S. Export Control Regulations
2. Export Administration Regulations (EAR)
3. The International Traffic in Arms Regulations (ITAR)
4. The Office of Foreign Assets Control (OFAC)

This peer-reviewed course was developed by a team of experts that included Steve Mackey at the University of Miami; Mark Bohnoht, JD at the University of Minnesota; Sara Conrad at the University of Nebraska-Lincoln; Peter Dunn, Ph.D at Purdue University; Kelly Hochstetler, Ph.D at the University of Virginia; Deborah Howard at the University of North Carolina at Chapel Hill; Sean Rubino, MPA at Texas A&M University; and Daniel Vick at the University of North Carolina at Chapel Hill. There is a small annual institutional fee to add this course to your institutional subscription to help defray development costs. In addition, the RCR for Engineers Course contains a module entitled, “The Researcher’s Role in Export Controls.”
Responsible Conduct of Research (RCR)
The CITI Program provides courses in the responsible conduct of research (RCR) to participating organizations. The courses include background text, interactive case studies, video vignettes and quizzes.

- NIH-recommended modules include Research Misconduct, Data Acquisition and Management, Responsible Authorship, Peer Review, Conflicts of Interest, Mentor-Student Relationships, Collaborative Research, Lab Animal Care and Use and Human Subjects Protections.
- Discipline specific courses are available for biomedical, social and behavioral, and physical sciences investigators and students.
- A course is available for people conducting scholarly activities in the humanities.
- RCR for Engineers focuses on the issues specific to the engineering research community.

RCR for Science Administrators provides research support staff with a basic understanding of their role in promoting the responsible conduct of research at their organization.

The RCR courses are customizable. Collections of textual materials or case studies can be specifically tailored to your learners.

Some RCR educational materials are now available in Spanish, Portuguese and Russian.

CITI recommends that RCR courses be used to provide a knowledge base for students and faculty prior to classroom meetings, small group discussions or other interactive activities.

Please contact The CITI Program to develop a RCR curriculum or to modify your current course design.

Help CITI Protect Your Learner’s Identity

The CITI Program can now be placed behind your institutional firewall or portal system on your institution’s intranet. The CITI Program’s Single Sign On offers several advantages:

1. Institutions can better control how learners access the CITI Program courses.
2. One less password to remember! Learners use the same authentication to login to your organization’s intranet and to the CITI Program.
3. Your organization has a user authentication process that adds considerable integrity to the web based training experience.
4. Data can be automatically delivered to your institutional training database or protocol management software.

Enrollment is easy! Ask your IT professional to contact the CITI Program support team for details. Call (305) 243-7970.
FORMER IRB ADMINISTRATOR, DR. JAIME ARANGO SHARES HOW TO GET THE MOST OUT OF THE CITI PROGRAM

Before you joined CITI Program, you were the Director of Human Subjects Protection Program at Nova Southeastern University (NSU), overseeing a diverse Human Subjects Protection program with 800 annual protocols and currently over 20,000 members. What sparked NSU’s decision to choose the CITI Program?

JA: We needed a systematic, well-developed package of content that was user-friendly and that ensured researchers, faculty and students would receive essential training. With CITI, modules and quizzes were already developed, reports were easy to extract, and the level of modifications that NSU could use to structure curriculum seemed limitless. The program becomes yours, partially because institutions have so much flexibility in customization. I encouraged NSU to pursue the CITI Program. It really was, and in my opinion continues to be, the best comprehensive solution.

What are your plans to enhance CITI’s human subjects research education?

JA: Institutions should know that we are listening. My job is to create a dynamic experience for our learners by integrating user feedback and quiz results into the courses. I monitor regulatory agencies for changes that affect researchers and subsequently the CITI Program’s content. Together with CITI Program’s well-recognized content developers—Dr. Gary Chadwick, Ms. Elizabeth Bankert, Ms. Ada Sue Selwitz, Ms. Cheryl Savini, Dr. Jeffrey Cohen and so many other respected contributors—we are actively keeping pace with our learners by challenging ourselves to create beneficial and relevant content. As a result, we have modified more than 30 HSR modules and launched two new GCP courses (with a new ICH focused drug program and an international-focused device program) within the past six months. Expect continued enhancements to the education process for learners and administrators—both within the modules and to the CITI Program’s system capabilities.

How will you help administrators?

JA: Administrators have a direct content person that they can work with, someone who shares the experience of being in their shoes. As a starting point, new administrators may contact me to help them devise a training strategy. I help administrators design their learner groups and select the subsequent modules to include in their curricula. One of the great qualities of the CITI Program is how much personalization the platform allows, but it can seem vast to some administrators. I can help them to truly tailor the CITI Program’s research education to their institutions’ needs.

Need help in planning your Human Research Subjects Curriculum?
Contact Dr. Arango at (305) 243-7970 or jarango@med.miami.edu.

Interested in becoming a content contributor?
We are always striving to enhance our content offerings to the research community. If you would like to submit your ideas, please send your suggestions to citiadmin@med.miami.edu.

CITI Program is looking for an education specialist. We are hiring an Assistant Director for Research Ethics and the Responsible Conduct of Research (RCR). If you want to learn more about this opportunity, please contact Adiper Santos at asantos2@med.miami.edu or call (305) 243-1598.
EVENTS CALENDAR
The CITI Program will be participating in the following conferences and meetings. Our representatives will be available to answer your questions or show you a course demo. **Drop by and say hello!**

### 2011 Schedule

**September 26-27 / ST. LOUIS, MISSOURI**

**OHRP NATIONAL RESEARCH FORUM AND COMMUNITY-ENGAGED RESEARCH CONFERENCE**

Hosted by Washington University School of Medicine’s Human Research Protection Office, Office of Human Research Protections, Meharry Medical College and the Washington University Institute of Clinical and Translational Sciences.

**October 22-26 / MONTREAL, QUEBEC**

**SRA INTERNATIONAL’S PORTAL TO RESEARCH: Navigating International Waters**

Visit CITI at booth # 28

**27-November 2 / ANAHEIM, CALIFORNIA**

**ABSA 54TH BIOLOGICAL SAFETY ASSOCIATION ANNUAL CONFERENCE**

Visit CITI at booth # 42

**November 6-9 / WASHINGTON, D.C.**

**NCURA'S ANNUAL MEETING**

Visit CITI at booth # 111

**December 1-4 / NATIONAL HARBOR, MD**

**PRIM&R ADVANCING ETHICAL RESEARCH CONFERENCE (AER)**

Visit CITI at booth # 201

**December 5-6 / SAN ANTONIO, TX**

**SCAW ANIMAL USE CONFERENCE**

Visit CITI’s booth in the exhibit hall

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Join us at our annual PRIM&R lunch on December 3rd!

Email registration@primr.org
HOW CAN WE HELP YOU?

The CITI Program Help Desk provides technical support and customer service to administrators and learners utilizing the CITI Program.

Support is offered via email, phone and live chat with technicians available to assist in English, Spanish, French, Portuguese, Arabic and Creole.

Questions? We have answers.
The CITI Program's Knowledge Base is a complete library of resources, hints, tips and answers to frequently asked questions regarding the CITI Program.

Visit our Knowledge Base at www.citiprogram.org/contactus.asp

GET EVEN FASTER RESPONSE WITH OUR LIVE CHAT
Have you used our live chat yet? The CITI Program’s customer support live chat makes it possible for you to get your questions answered immediately.

We encourage you and your learners to utilize our live chat services. Here are a few of the benefits to using Live Chat:

- The CITI Program’s live chat is free! There are no additional fees for live chat or any software downloads required.
- It is easy to use. Have a question while taking a course? Live chat allows you to get assistance without having to step away from your computer. There are no wait times—you receive instant responses to your inquiries.
- Keeps the same personalized experience as a phone call. Our live chat is run by our help desk, and not outsourced.
- Reduce costs. Live chat can save your institution on outbound telephone costs.
- Global access: Live chat support is supported across geographic boundaries, providing a unified customer support platform for real time trouble shooting in multiple languages.

LIVE CHAT IS AVAILABLE MONDAY THROUGH FRIDAY 8:30AM TO 5:00 PM EST.

ASK CITI SUPPORT

How many administrators can my institution have?
We allow each institution to have an unlimited number of administrators. You can even specify administrators’ access by discipline area, such as Human Subjects or Lab Animals.

Can our institution set up custom modules? What is the process?
Yes! After sending us the material you wish to include in the custom module, it is reviewed and a work time estimate is given. The technician will use programming language to make the content uniform to the CITI Program website. Once the process is complete, you will have the chance to review the module before it goes live.

There is a fee of $80/hour to set up custom modules.

Many of your questions can be answered at CITI’s Knowledge Base Please visit www.citiprogram.org/contactus.asp

Are You New To The CITI Program?
SIGN UP FOR THE NEXT ADMINISTRATOR WEBINAR
Webinars are offered to Institutional CITI Administrators ongoing basis, free of charge. Topics include the administrative menu, running reports, customizing the curriculum and other institutional information.

Visit the Knowledge Base for the Webinar Schedule
www.citiprogram.org/contactus.asp
## CITI COURSES

### HUMAN SUBJECTS RESEARCH (HSR) - BIOMEDICAL MODULES*
- Belmont Report and CITI Course Introduction
- History and Ethical Principles
- Basic Institutional Review Board (IRB) Regulations and Review Process
- Informed Consent
- Social and Behavioral Research for Biomedical Researchers
- Records-Based Research
- Genetic Research in Human Populations
- Research With Protected Populations - Vulnerable Subjects: An Overview
- Vulnerable Subjects- Research With Prisoners
- Vulnerable Subjects- Research Involving Minors
- Vulnerable Subjects- Research Involving Pregnant Women and Fetuses in Utero
- Avoiding Group Harms: U.S. Research Perspectives
- Avoiding Group Harms: International Research Perspectives
- FDA-Regulated Research
- Stem Cell Research Oversight Parts I and II

### HUMAN SUBJECTS RESEARCH (HSR) - SOCIAL & BEHAVIORAL RESEARCH (SBR) MODULES*
- Belmont Report and CITI Course Introduction
- History and Ethical Principles – SBR
- Defining Research with Human Subjects – SBR
- The Regulations and The Social and Behavioral Sciences – SBR
- Assessing Risk in Social and Behavioral Sciences – SBR
- Informed Consent – SBR
- Privacy and Confidentiality – SBR
- Research with Prisoners – SBR
- Research with Children – SBR
- Research in Public Elementary and Secondary Schools – SBR
- International Research – SBR
- Internet Research – SBR

### HUMAN SUBJECTS RESEARCH (HSR) - ADDITIONAL MODULES*
- International Studies
- Human Subjects Research at the VA
- Research and HIPAA Privacy Protections
- Vulnerable Subjects - Research with Workers/Employees
- Conflicts of Interest in Research Involving Human Subjects
- Students in Research
- You want to be an IRB Community Member, Now what?
- The IRB Administrators’ Responsibilities
- IRB Member: What Every New IRB Member Needs to Know

* Refresher courses available on selected modules

### GOOD CLINICAL PRACTICE (GCP) — U.S. FDA FOCUS MODULES
- Overview of New Drug Development
- International Conference on Harmonization(ICH):GCP Requirements
- International Conference on Harmonization-ICH for Investigators
- Conducting Investigator-Initiated Studies According to FDA Regulations
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Conducting Clinical Trials of Medical Devices
- Informed Consent : An Ongoing Process
- Detection and Evaluation of Adverse Events
- Reporting Serious Adverse Events
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections in Clinical Trial

### GOOD CLINICAL PRACTICE (GCP) COURSE FOR CLINICAL TRIALS WITH INVESTIGATIONAL DRUGS (ICH FOCUS) MODULES
- Conducting Investigator-Initiated Studies According to FDA Regulations
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Informed Consent in Clinical Trials of Drugs
- Monitoring of Clinical Trials of Drugs by Industry Sponsors
- Audits and Inspections in Clinical Trials
- Overview of New Drug Development
- ICH Overview
- ICH—Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Detection and Evaluation of Adverse Events
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics

### GOOD CLINICAL PRACTICE (GCP) COURSE FOR CLINICAL TRIALS WITH INVESTIGATIONAL MEDICAL DEVICES MODULES
- Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Devices According to GCP Requirements
- Conducting Clinical Trials of Medical Devices
- Informed Consent in Clinical Studies of Devices
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections in Clinical Trial
- Reporting Requirements for Device Studies

* Refresher courses available on selected modules
CITI COURSES

RESPONSIBLE CONDUCT OF RESEARCH (RCR) MODULES
• Research Misconduct
• Data Acquisition, Management, Sharing And Ownership
• Publication Practices And Responsible Authorship
• Peer Review
• Mentor And Trainee Responsibilities
• Conflicts Of Interest and Commitment
• Collaborative Research
• Human Subjects
• Animal Welfare
• RCR for Administrators Course
• RCR for Engineers Course

ANIMAL CARE AND USE – MULTIPLE SPECIES COURSES
• Working With the IACUC
• Essentials for IACUC Members
• Post Procedure Care of Mice and Rats in Research: Reducing Pain and Distress
• Aseptic Surgery
• Antibody Production
• Working with Amphibians in a Research Setting
• Working with Cats in Research Settings
• Working with Dogs in Research Settings
• Working with Ferrets in Research Settings
• Working with Gerbils in Research Settings
• Working with Guinea Pigs in Research Settings
• Working with Hamsters in Research Settings
• Working With Nonhuman Primates in Research Settings
• Working with Mice in Research Settings
• Working with Rabbits in Research Settings
• Working with Rats in Research Settings
• Working With Swine in Research Settings

HEALTH INFORMATION PRIVACY AND SECURITY (HIPAA) MODULES
• The HIPS-HIPAA Education Series
• Privacy Rules: Introduction to Federal and State Requirements
• Privacy Rules Modules: Clinicians, Students, Instructors, Fundraisers and Marketers
• Security Rules: Basics of Being Secure, Part 1 and 2
• Security Rules: Protecting your Computer
• Security Rules: Picking and Protecting Passwords
• Security Rules: Protecting your Portables
• Security Rules: Protecting your Identity
• Security Rules: Safer Email and IM, Part 1 and 2
• Security Rules: Safer Web Surfing
• Security Rules: Introduction to Federal and State Requirements
• Security Rules: Issues for Work/Workers Offsite

BIO-SAFETY AND BIO-SECURITY MODULES
• Biosafety Course Overview
• Laboratory-Associated Infections
• Biohazard Risk Assessment
• Medical Surveillance
• Risk Management - Work Practices
• Work Safely with Sharp Instruments
• Disinfection and Sterilization
• Risk Management - Personal Protective Equipment
• Risk Management - Emergency and Spill Response
• Risk Management - Engineering Controls
• Centrifuge Precautions
• Safe Sharps Devices
• Risk Management - Laboratory Design
• OSHA Bloodborne Pathogens Standard
• NIH Guidelines for Research Involving Recombinant DNA Molecules
• Human Gene Transfer Research
• Select Agents
• Biosecurity
• Bioterrorism
• Shipping Regulated Biological Materials
• Animal Biosafety
• Understanding Nanotechnology and its Implications

EXPORT CONTROL REGULATIONS MODULES
• U.S. Export Controls – General Overview Modules
• Export Administration Regulations (EAR)
• The International Traffic in Arms Regulations (ITAR)
• The Office of Foreign Assets Control (OFAC)

2.8 million people around the world have completed the CITI Program’s courses. Let us help you design a personalized curriculum for your institution. Contact us to set up a demo.