IRB Grand Rounds

Education and Training with Respect to Human Subject Protections, Good Clinical Practice, and Clinical Research Coordinators

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CITI Program

Learning Objectives

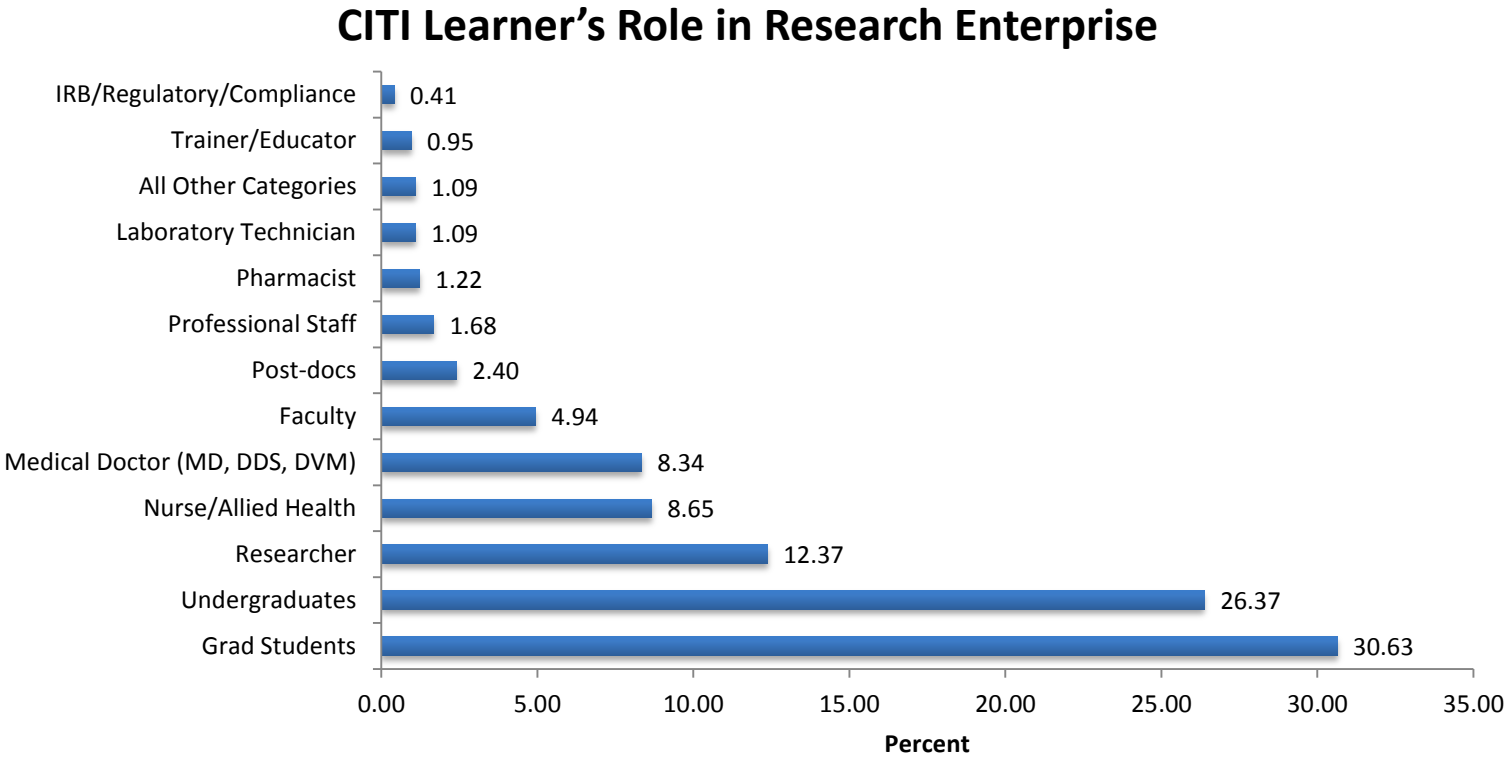
By the end of this presentation, you will be able to:

- Identify requirements for human subjects research training.
- Describe the structure of the CITI Program training.
- Illustrate how CITI Program content may be used by the IRB to address researcher non-compliance.
- Utilize the CITI Program tools to best meet training needs.

Quick Poll

- What is your role in research here at UM/JHS?
  - IRB Administrator / Staff
  - IRB Member
  - Researcher
  - Compliance Officer
  - Grad Student
  - Something else?

Most CITI Program learners are … Students



What's my role?

- 5 years at the UM HSRO as an IRB analyst
  - Reviewed over 600 items/year
  - Ran 12 IRB meetings/year
  - Worked mainly with biomedical IRB-B
- Joined CITI Program in March 2014
  - Content management and development for HSR/GCP
  - Assisting institutions to determine best training options for their needs
  - Review learner feedback quarterly

REQUIREMENTS FOR HUMAN SUBJECT TRAINING AND EDUCATION

Why do you need training?

- Human research in the past has not always been ethical
  - Nuremberg
  - U.S. Public Health Service (PHS) Study of Untreated Syphilis
  - STD Research in Guatemala
- Issues in research today require ethical reasoning

Goal of Training = Subject Safety

Who contributes to ensuring subject safety?

- Regulations (21 CFR, ICH, Standards, Local Law)
- IRB/IEC
- Sponsor
- Research team (PI, CRC, study staff)

Training is required by:

- Federal Agencies
- Institutional / Organization
- Sponsors
- GCP guidelines
- Professional Certifications / Boards

Example 1: UM/JHS- Required training

- UM has an education policy that requires all UM/JHS human subjects researchers to complete training in Human Subjects Protection regardless of the researchers' funding source, or study risk-level

UM HSRO Policy: HRP-101

Education and Training

IRB members, IRB staff, and others involved in the review of Human Research must complete initial and continuing training.

Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

Avoiding delays

Until researchers are trained, they can't work on the research study.

In my experience at the HSRO, this caused an avoidable delay in researchers receiving their IRB approval letters.

Make sure your training is both complete and current.

Example 2: GCP

The principles of ICH GCP E6 include:

- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

(International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). 1996. "ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6(R1)." Accessed February 16, 2015.)

Training and Education are not Everything

- Training is important, but so is mentoring
- Web-based modules are not meant to be the end-all of research ethics education
- Competency based assessments should still be used in research roles
- The use of knowledge based assessments (completion quiz) can help assess if learners know the material

Proactive Measures to Increase Compliance

- Training and education
- Compliance is bred in a proactive environment
  - The culture of being able to ask questions
  - Training sets up-front expectations and increases consistency of knowledge for everyone
  - Training doesn't replace experience

Who needs training?

Basically, everyone in research

Researchers, IRB members, IRB admins, CRCs

Example: For NIH-funded research (FAQs)

Who needs to receive required education on the protection of human subjects?

- Individuals who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the education requirement.

Are investigators involved in human subjects research that is described by one or more of the exemptions in 45CFR46 required to comply with the education requirement?

- Yes.

Does the education requirement apply to Key Personnel involved in human subjects research supported by an NIH award if they will not be compensated by the award?

- Yes.

Do Key Personnel on foreign awards or on foreign subcontracts have to comply with the education requirement?

- Yes.

Do third party (subcontract) Key Personnel or consultants need to comply with the education requirement?

- Yes.

Is not being trained really that bad?

Example: FDA 483 Observational Summaries

In FY 2014, many FDA 483 Observational Summaries of Drug studies cited lack of training.

In drug studies:

- 33 letters stated that employees engaged in the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] required to perform their assigned functions.

In device studies:

- 2 letters stated that the investigator(s) not qualified by training to investigate a device
- 61 letters stated lack of training or inadequate procedures for training and identifying training needs
- 38 letters stated lack of training records / personnel training is not documented
- 12 stated that personnel do not have the necessary do not have the necessary [education] [background] [training] [experience] to perform their jobs.

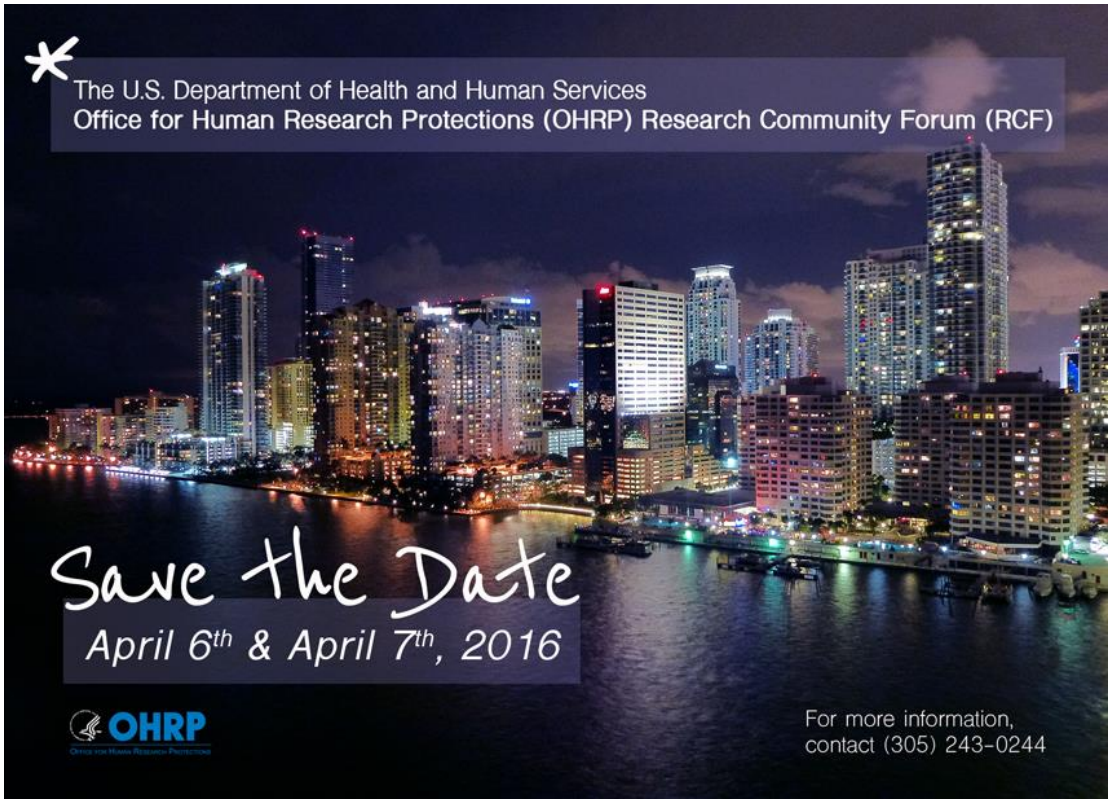
What training resources are available?

- Attend conferences
  - OHRP (Research Community Forums, Quality Assessment Workshops)
  - PRIM&R
  - ACRP
- Webinars (OHRP, FDA)
- Websites
  - OHRP, PRIM&R, NIH, FDA
- Web-based Learning Modules (CITI Program, NIH modules)

Human Subjects Research Training Available at UM

- CITI Program
- UM HSRO
  - Grand Rounds
- UM Office of Research – Research Compliance & Quality Assurance (RCQA)
  - Regular and ongoing human subjects educational training sessions covering preparing for an FDA Audit, Responding to FDA Observations, ClinicalTrials.gov, etc.
- OHRP Research Community Forum (RCF) – April 2016

Save the Date – OHRP Miami RCF



The U.S. Department of Health and Human Services
Office for Human Research Protections (OHRP) Research Community Forum (RCF)

APRIL 6TH, 2016
RCF Pre-Conference Workshop

APRIL 7TH, 2016
RCF Conference

LOCATION
Marriott Miami Biscayne Bay Hotel
1633 N Bayshore Drive
Miami, FL 33132

EMAIL FOR MORE INFO
citisales@med.miami.edu

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CITI PROGRAM TRAINING

BEFORE I started working here – What I knew about the CITI Program

- You could call them for help and speak to a real person
- The website got easier to use to check study team's CITI course completions a few years ago
- UM has different learner groups for the types of human subject research

7 Things I've learned…

1. How big is the CITI Program today
2. What's the difference between series, courses and modules
3. The additional modules of interest really can be interesting. And helpful.
4. You can access content that's not included in your learner group
5. The Help Desk does more than help you remember your password.
6. There are different GCP courses and knowing which one to take is important.
7. You can contribute and suggest new content.

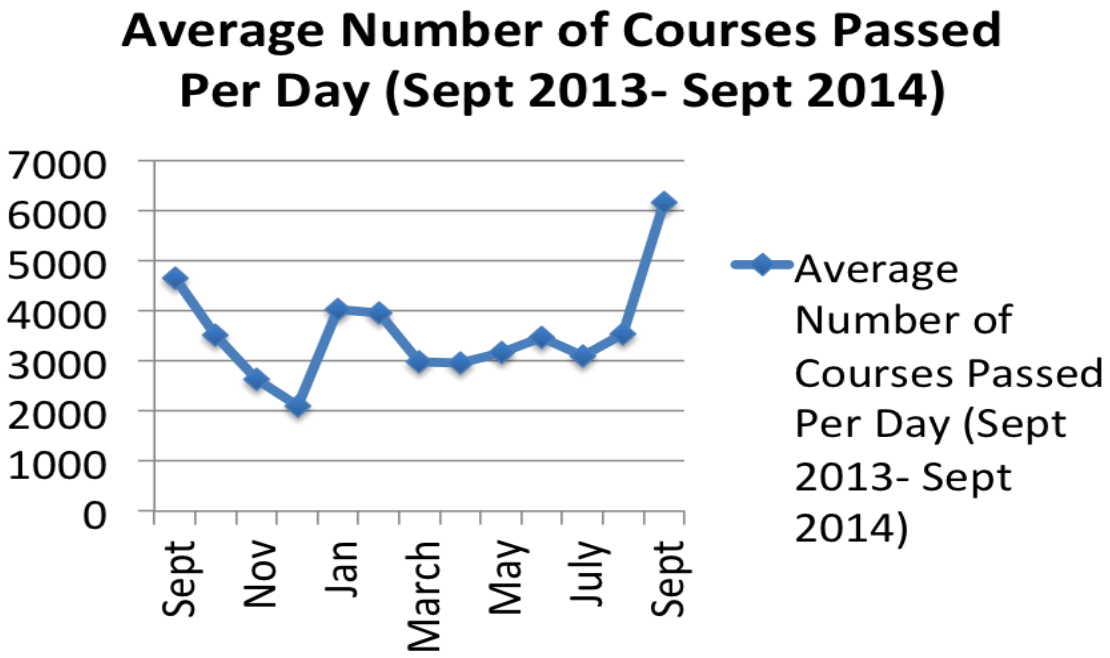
1. How big is the CITI Program today?

7.2 million courses completed since 2000

CITI Program Stats

- CITI Program is subscription-based with over 2900 institutions from around the world
- ~50,000 new learners per month complete a CITI Program course
- There are close to 4.7 million CITI Program accounts
- 73,000 members have logged into CITI within the last 30 days

CITI Program Usage



3,555 courses were passed per day on average from 2013-2014

UM/JHS learners are using the CITI Program

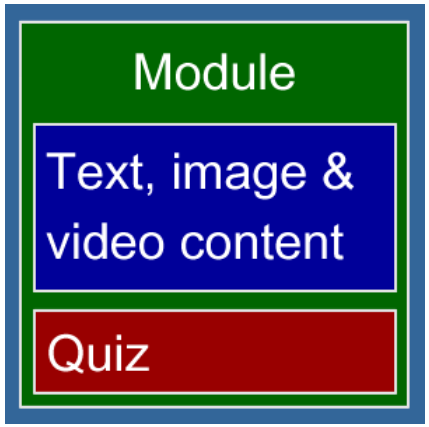
Top 5 Institutions	Number of Courses Passed (Sept 2013-Sept 2014)
City University of New York (CUNY)	16,298
Greater Cincinnati Academic and Regional Health Centers	13,740
#3 University of Miami / Jackson Health System	12,583
Wayne State University – Detroit, MI	12,559
University of Pittsburgh	11,892

2. What's the difference between modules and courses and series?

CITI Program is structured with series, courses, and modules.

Modules

- Content is organized into **modules** which can be thought of as lessons
- Modules are generally length-restricted so as to require at most 20 minutes for the average learner to complete.
- Modules typically include a quiz; achieving a passing score is required to complete the module



CITI Program Structure

There are 10 main series:

- Animal Care and Use (ACU)
- Biosafety and Biosecurity (BSS)
- Clinical Research Coordinator (CRC)
- Disaster Planning for the Research Enterprise (DPRE)
- Export Control (EC)
- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Human Subjects Research (HSR)
- Information Privacy and Security (IPS)
- Responsible Conduct of Research (RCR)

HSR Series

- >134 HSR modules
- HSR Courses include:
  - Biomed Track - Basic and 3 Refreshers
  - Social, Behavioral, and Educational Track (SBE) -Basic and 2 Refreshers
  - Institutional / Signatory Official: Human Subject Research Course
  - IRB Administration Course
  - IRB Chair Course

GCP Series

GCP Courses include:

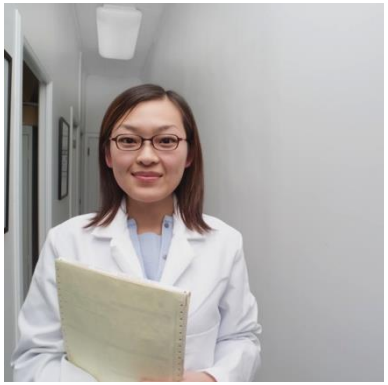
- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) Course
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) Courses - Basic and Refresher
- GCP for Clinical Trials with Investigational Medical Devices Course

Coming soon – GCP Device Refresher Course (Summer 2015)

New – Clinical Research Coordinator (CRC) Course

Basic CRC Course

- Intended for CRCs, investigators, and other clinical research professionals or those pursuing a career in clinical research.
- Modules include:
  - CITI CRC Course: Overview
  - Planning Research
  - Funding, Financial Management, and Budgeting
  - Working with the IRB
  - Protocol Review and Approvals
  - Principal Investigator (PI) Responsibilities
  - Clinical Research Coordinator (CRC) Responsibilities
  - Sponsor Responsibilities
  - Informed Consent
  - Site Management, Quality Assurance, and Public Information
  - CRC Resources



3. The additional modules of interest really can be interesting. And helpful.

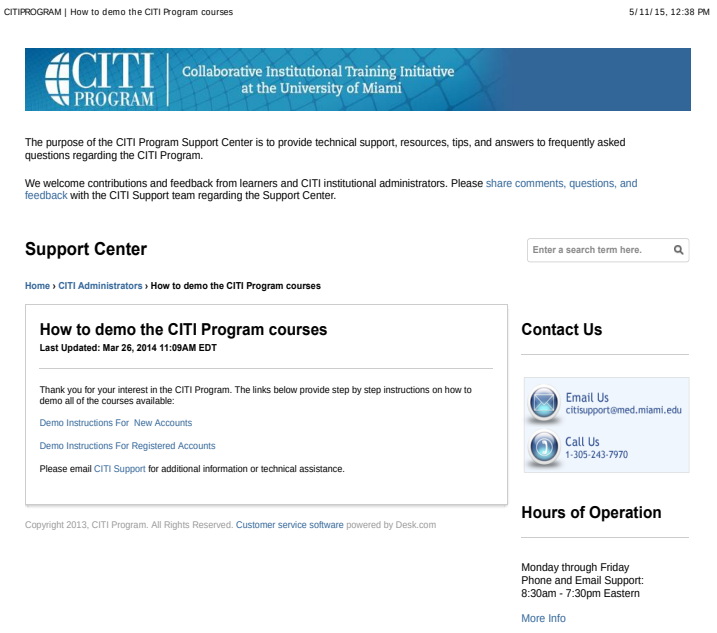
Additional Modules of Interest

- Cultural Competence in Research
- Conflicts of Interest in Research Involving Human Subjects
- External IRB Review
- Hot Topics
- Humanitarian Use Devices (HUDs)
- I Have Agreed to be an IRB Community Member. Now What?
- International Studies
- Students in Research
- The IRB Administrator's Responsibilities
- The IRB Member Module - "What Every New IRB Member Needs to Know"
- Vulnerable Subjects - Research Involving Workers/Employees
- Stem Cell Research Oversight (Part I)
- Stem Cell Research Oversight (Part II)
- Research with Decisionally Impaired Subjects
- Research with Critically Ill
- Gender and Sexuality Diversity (GSD) in Human Research
- Research with Persons who are Socially or Economically Disadvantaged
- Research with Older Adults
- Illegal Activities or Undocumented Status in Human Research
- Research Involving Subjects at the End of Life
- Research with Subjects with Physical Disabilities & Impairments

4. You can review content that's not included in your learner group

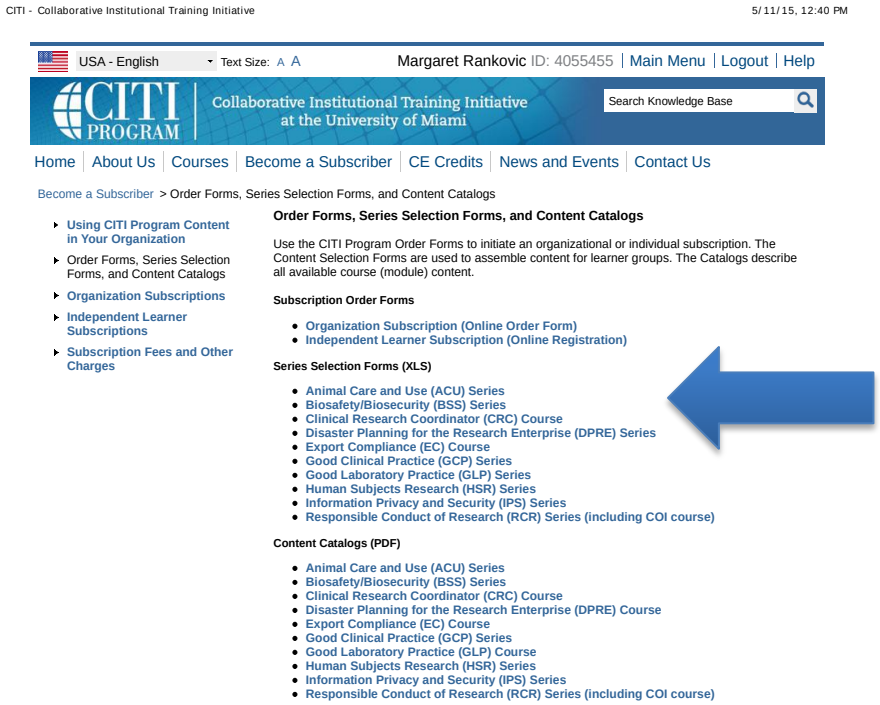
- Use DEMO Affiliation to **review** any module
  - Allows access to all of the CITI Program modules, including complete review of the module and associated quiz
  - Does not affect your standard affiliation

Note: to access content to earn a **completion report, you need to add a new course through UM/JHS or via Independent Learner



How to find content

- All content is listed on the series selection forms, and described in the content catalogs



5. The Help Desk does more than help you remember your password.

The CITI Program Help Desk (HD) handles technical support request from course takers and institutional administrators via email and phone

But most requests are for passwords

Most Common Requests

- Forgotten username/password
- Merge duplicate accounts
- Questions about scores
- General navigation of the website

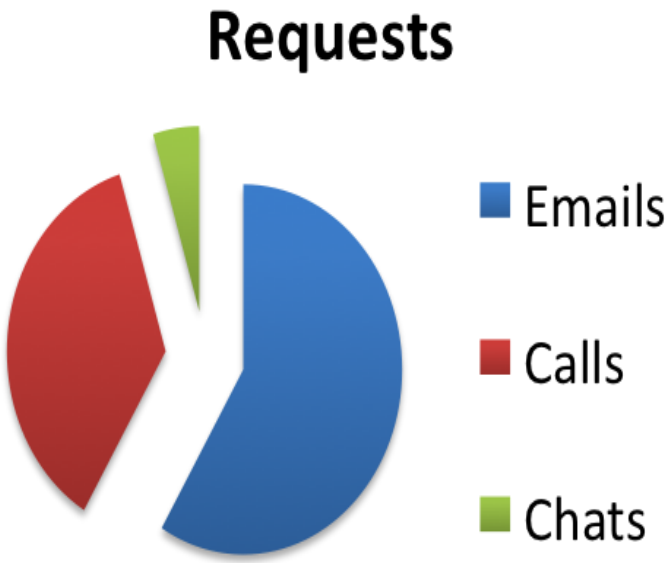
Help Desk:
phone, email, knowledgebase

91,993 Cases were Resolved During the Past 12 Months

Over the past 12 months, 59% of all request to the help desk have been email, 37 % have been calls and 4% were live online chats.

From Sept 2013- Sept 2014

- **58,470 Email Requests**
  4,872 Monthly Average
- **36,620 Phone Calls**
  3,052 Monthly Average
- **4,686 Live Chats**
  390 Monthly Average



Note: there are many self-help tools on the CITI Program website to resolve inquiries on one's own

6. There are different GCP courses and knowing which one to take is important.

Types of GCP training: Identifying the right training for you

- **Do you want an International (ICH) or USA (FDA) focus?**
- **Do you want a device-focused program?**
- **Have you already completed a basic course?**
- **Do you want training that has been recognized by TransCelerate BioPharma for meeting their minimum criteria?**

Example: TransCelerate BioPharma → ICH E6 GCP Investigator Site Training

The CITI Program has **five** GCP courses that have met the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

But there are three GCP courses that have not met the Minimum Criteria.

7. You can contribute and suggest new content.

Contact the CITI Program if you have an idea for new content or if you think there is content area missing from the current CITI Program

- Examples include the Humanitarian Use Devices module

Other ways to be involved

- You can be a peer-reviewer of new CITI Program content.
- You can also submit feedback through the learner feedback tool, or contact the Help Desk (citisupport@med.miami.edu).

CITI PROGRAM TRAINING AND EDUCATION TO ADDRESS NON-COMPLIANCE

How can the CITI Program training help the IRB ?

IRB Administration Course

This course provides members of the Institutional Review Board's (IRB) administrative office (administrators, directors, coordinators, and other support staff) with a comprehensive review of the critical areas associated with IRB and IRB office operations.

- Modules
  - HRPP/IRB Policies and Procedures
  - Reporting to Federal Agencies
  - Communicating with Subjects
  - Internal Quality Assurance and Quality Improvement of the HRPP
  - External Oversight of the IRB/HRPP: Monitoring and Inspections

IRBs can also use CITI Program content

- To address training needs before study initiation to prevent potential non-compliance
- To address researcher non-compliance through further training

Example: During Initial IRB Review

During initial IRB review, the IRB may note that the proposed research includes a topic that the PI/study team may need further training in.

For example, a proposed study includes subjects who are over 70 years of age. The IRB may recommend or require the PI/study team complete the CITI Program module *Research with Older Adults.*

Example: During Review of an Audit Report

When non-compliance is reported to the IRB, the IRB can determine if further training is required and ask the PI/study team to complete specific modules.

For example, a monitoring report indicates that the PI/study team did not properly document consent. The IRB may recommend or require the PI/study team complete the CITI Program module *Informed Consent*.

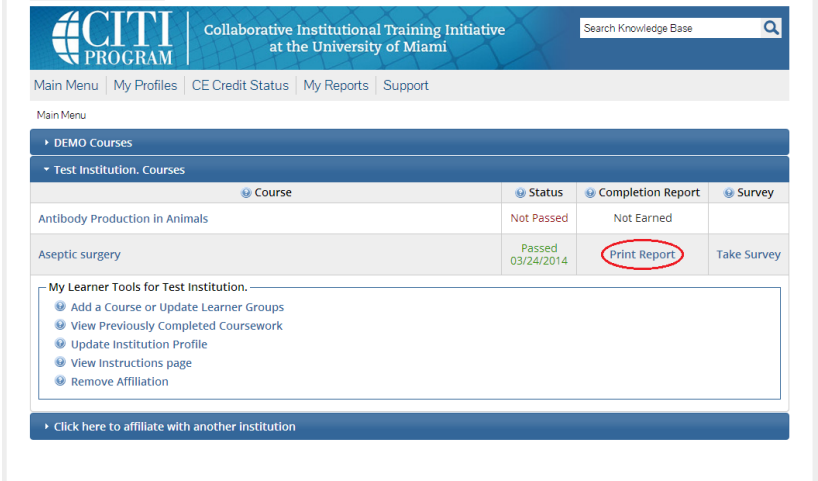
CITI PROGRAM TOOLS TO BEST MEET TRAINING NEEDS

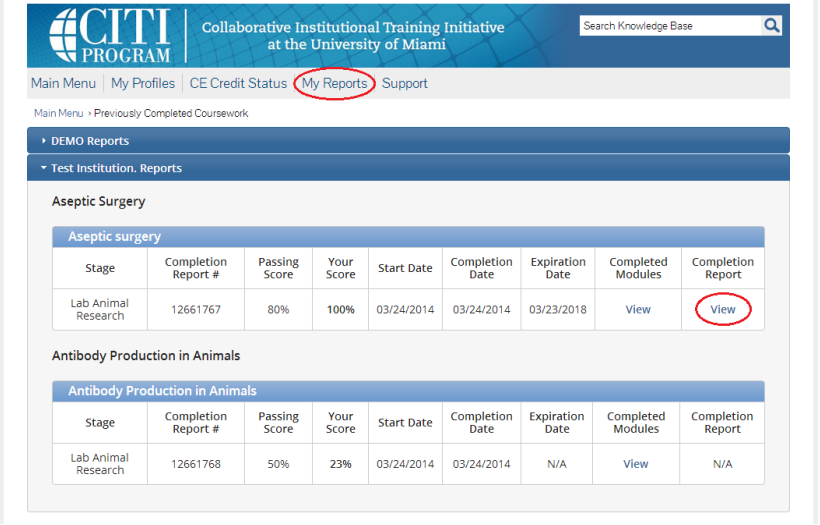
There are more courses than ever for specific research roles.

- IRB Administrator
- IRB Chair
- IO/SO
- CRC

Reports are just a click away.

- Learners can access their own completion reports online
- Administrators can also access learner completion reports





Guidebooks and Binder Tabs are also available.

CITI Program content can help in your professional areas of interest

- CE credit
  - Besides fulfilling institutional training requirements, learners can also earn CE credits.
- CIP exam
  - Reviewing CITI Program content is a great study tool for CIP exam

CE Credits and Units

- CE credits and unit types
  - Offered to organization-affiliated and independent learners
  - Cost an additional separate fee (not the same as the completion report)
  - Information is on CITI Program website (including a Guide and FAQs, and which courses/modules have CE credits)
  - Different types of credits are available (Physicians, Nurses, etc.)
- Earning CE credits and units is easy
  - Prior to starting the course(s), click “MyCEUs” tab located on the “Main Menu” page, and check “Yes,” indicate type of credit, and click “Submit.”

CE Credits and Units

Step 1: Request CEU credit

CE Credits and Units

Step 2: Purchase CEU credits

How to Contact the CITI Program

- You can contact me directly about content related questions or comments
- Contact the Help Desk (email or phone)
- Check out the CITI Program website – www.citiprogram.org (newsletter and announcement archives, knowledge base FAQs)

Questions

THANK YOU!