

Collaborative Institutional Training Initiative

CITI Newsletter



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Collaborative Institutional Training Initiative (CITI) Program – now offering a full complement of educational resources for the global research community

Most people probably don't realize how much CITI has grown over the past 10 years. What started as an online training tool for human subjects research has grown into a resource rich virtual library where modules, materials and information related to research ethics can be used to develop and present research ethics curriculum to specific target audiences at our participating institutions and organizations around the world.

Remember to update your institutional training profile with CITI to add access for your learners to any of the new or existing content offerings by contacting the CITI Office by e-mail at citisupport@med.miami.edu or by phone at 305 243-7970

New Projects

A. CITI Administrator Webinars

A new feature for the CITI Program is the CITI Institutional Administrator's Webinar series. The webinar series is designed to help the CITI institutional administrator keep up to date on the newest features in the CITI Program. In addition the CITI Webinar series permit the Institutional Administrators to get the most from the CITI Program for their students, faculty and staff. Currently, there are 3 different Webinars in the series each more advanced than the previous.

The topics covered included:

- The role of a CITI Institutional Administrator.
- Functions of the Administrator Menu and administrator utilities.
- Customizing your institution's course curriculum using CITI Forms.
- Working effectively with the CITI support desk.

For more information on this new resource Visit our Knowledge Base site for time and date information. <http://citiprogram.supportcenterpro.com/knowledgebase> . These 30 minute Webinars conducted by CITI Content specialists have become very popular. It is important to RSVP early as space is limited.

B. CITI Biosafety Course

We continue to review and consider topical areas of need for our research community.

The new CITI Biosafety Course will be available to CITI participating institutions in February 2010. Please see the Biosafety Library contents listed below. From this library CITI content experts have developed a number of recommended curriculum options for several learner groups including:

- Institutional Biosafety Committee Member Training.
- Biosafety Officer Initial Training Series.
- Basic Introduction to Biosafety.
- Initial Investigator Biosafety Training.
- Biosafety Retraining
- Lab Animal Biosafety.
- Shipping and Transport of Regulated Biological Materials.
- OSHA Bloodborne Pathogens.
- Select Agents, Biosecurity and Bioterrorism.
- Emergency and Incident Response to Biohazard Spills and Releases.
- Human Gene Transfer and NIH Recombinant DNA (rDNA) Guidelines
- OSHA Personal Protective Equipment Training.

If you believe that your institution will be interested in using this new resource, please contact the CITI Office to obtain access for your organization. The course will initially be available without additional charge to your institution to review and to evaluate. However, due to the considerable production costs associated with the development of this new resource, on June 1, 2010, CITI will begin adding a \$500/year surcharge to the annual institutional user fee for institutions who want to use this new course for their research faculty, staff and students.

Modules in the CITI Biosafety Library

1. Biosafety Course Overview	
2. Laboratory-Associated Infections	
3. Biohazard Risk Assessment	
4. Medical Surveillance	
5. Risk Management - Work Practices	
	5.1 Risk Management - Work Practices
	5.2 Work Safely with Sharp Instruments
	5.3 Disinfection
	5.4 Safe Pipetting and Miscellaneous Work Practices
6. Risk Management - Personal Protective Equipment	
7. Risk Management - Engineering Controls	
8. Risk Management - Laboratory Design	
9. Risk Management – Emergency Procedures	
10. OSHA Bloodborne Pathogens	
	10.1 Bloodborne Pathogens
	10.2 Hepatitis B Virus Vaccination and Exposure Routes
	10.3 Labels & Engineering Controls
<i>Continued...</i>	

11. NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules	
12. Human Gene Transfer Research	
13. Select agents and Biosecurity	
	13.1 Select Agents
	13.2 Biosecurity
	13.3 Bioterrorism
14. Shipping Regulated Biological Materials	
	14.1 Shipping Regulated Biological Materials: Overview - 1
	14.2 Shipping Regulated Biological Materials: Classifications - 2
	14.3 Shipping Regulated Biological Materials: Packaging Requirements - 3
	14.4 Shipping Regulated Biological Materials: Shipping Papers - 4
	14.5 Shipping Regulated Biological Materials: Permits for Restricted Shipments - 5
	14.6 Shipping Regulated Biological Materials: Security Awareness - 6
	14.7 Shipping Regulated Biological Materials: Emergency Response - 7
	14.8 Shipping Regulated Biological Materials: Refrigerants - 8
	14.9 Shipping Regulated Biological Materials: Appendix - 9
15. Animal Biosafety	
16. Understanding Nanotechnology and its Implications	

The current CITI Program Content Library includes courses in:

A. Human Subjects Protections, including specific courses for :

- Biomedical Researchers
- Social and Behavior Researchers
- Researchers conducting stem cell research (ESCRO) – New for 2010
- IRB Members
- IRB Administrators – New for 2010
- Community IRB Members – New for 2010

B. Good Clinical Practice. – completely updated in summer 2009.

- Many of these modules are now available not only in English, but, also in Spanish, Portuguese, Chinese, Korean, Thai and soon to be posted, in French.
- The Public Access International Platform resource for institutions collaborating in research at international sites now has a new address. The site, formerly located at irbtraining.org, has moved to the main CITI site. Just click on the International tab at www.citiprogram.org. There were three basic modules translated from English to Spanish, Portuguese, Chinese and French.

C. Health information protection and security (HIPS)

- HIPAA Privacy and Security Rules
- Other modules devoted to keeping your computers, electronic media, data, and your identity safe and secure.

D. Responsible Conduct of Research

- Courses are now available for the Biomedical, Social and Behavioral, Humanities and Engineering research. In addition, a course for Research Administrators is also offered. These courses can be used to meet the NSF mandate for RCR training and to partially fulfill the updated NIH mandate for training of NIH supported students and fellows in the RCR.
- CITI hired a science and technology editor to resolve many of the outstanding issues in the CITI RCR modules. The contractor reviewed and made editorial changes to all of the RCR modules. These changes were implemented in mid January 2010.
- The recent NSF and NIH mandates for RCR education for students and faculty researchers has created a substantial burst of activity at the CITI Program to provide high quality training materials. More than 90 new institutions and organizations have joined the CITI program in the past three months.
- New RCR Course for the Humanities – Implemented in February, 2010.
- A revised RCR Course for the Social and Behavioral Researcher (SBR) is under development with a target roll out date of June 1, 2010
- Three new introductory video case studies have been added to the course site to enhance the RCR learning experience. These new video vignettes cover Research Misconduct, Data Acquisition and management and Conflicts of Interest. We are currently looking for innovative approaches to get more people to review these video cases before beginning the module.

E. Lab Animal Welfare

- Courses are available for the research investigator and the IACUC member.
- Other species/animal model specific courses are also available for member institutions to meet the federal training mandate.
- Refresher courses are currently under development.

If you would like to add any of these courses or new modules to the curriculum offerings for your institution, please contact the CITI Office by email at citisupport@med.miami.edu or by phone at 305 243-7970.

Collaborative Institutional Training Initiative - International

CITI continues to increase its presence around the world. We are now available at more than 1350 sites around the globe. Sixty-five sites are located in 38 countries outside the United States.

The international working group is striving to develop sustainable CITI Programs for the international research community. CITI Centers of Excellence have been established in: Latin America, Taiwan, Japan, Korea, India, the Middle East, and Canada. For two years now, the CITI site has been a

multi-language course site and was updated in both 2008 and 2009 to accommodate non English character sets. CITI course work is now available in the following languages (funding source): English, Spanish (NIAID, FIC), and Portuguese (NIAID, FIC), Chinese, Japanese, French (NIAID), *Thai (US Army)*, Russian (*US Army*), Korean, *Kartuli (FIC)*, *Arabic*

In Other International News

A. India:

CITI leaders are collaborating with the Sri Ramachandra University (SRU) in Chennai, the capital city of the state Tamul Nadu in India. In November 2009, CITI together with Drs SP Thyagarajan and B.W.C. Sathiyaskekaran at SRU together with OHRP sponsored a conference entitled "Promoting Research Ethics Education in India". Over 300 researchers from



academia, industry and the Indian government attended the 3 day meeting.

Representing CITI were Paul Braunschweiger, Mansoor Ahmed, Ram Agarwal, Ail Sharma, Melody Lin, Chi Lin and Jerry Castellano. In addition to very informative presentations about the state of research ethics education in India, a full half day of the meeting was devoted to the development of a new program initiative, CITI-India.

Sri Ramachandra University, partnering with Harvard Medical International, is home to more than 43,000 students including medical, pharmacy, nursing and dental schools.

B. Updates from Taiwan

CITI use continues to expand with 3296 investigators receiving completion certificates for CITI human subject's modules; an additional 858 research assistants, 528 IRB members, and 269 researchers under Taiwan's central IRB have also received CITI certificates from the completion of human subjects modules.

Plans for CITI-Taiwan include enhancements of the CITI Chinese version to be more user friendly for non-scientific IRB members. There are also plans to translate the RCR and GCP modules to Chinese. The group is undertaking the creation of a Human Subject Protection Association (HuSpat) in Taiwan. This "PRIMR- like" group will continue to promote research ethics and education.

CITI Hardware and Software Updates

Hardware - In August of 2009, new hardware was purchased which resulted in 4 new web servers; 2 new database servers and 3Tb back up hard drive. This has allowed us to triple the computing capacity, allowed code rewrites to improve efficiency as part of the transition to new servers; improved database backups, and improved training record downloads. Currently the system is rated at between 2500 and 3000 concurrent users.

With different options available for training sessions and with individuals transferring from one location to another, CITI is now capable of allowing institutions, at their discretion, to issue "credit" to learners who completed coursework for another institution. Additionally, didactic sessions (those completed outside the CITI platform) can be recorded and tracked by institutions and learners. There is a plan to implement an automated method for institutional administrators to assign new coursework to groups or subgroups of learners.

User feedback - We take the feedback we receive seriously and review it constantly with an eye on making the site, the courseware and the entire program as useful and user friendly as possible. For example, changes to the Learner's Menu were made to make it more intuitive and user friendly.

Other new functions include the ability to permit institutions to issue "back credit" if they so choose to individuals who've completed modules at some time in the past. This function could be especially useful to individuals who have moved from one institution to a new one by allowing the new institution to consider giving credit for previously completed modules and course work.

Portal Access - CITI is now offering a solution to permit institutions to put their institutional access to the CITI Program behind the institutional firewall or portal. Five institutions are using the Portal system at this time and 6 are already in line for implementations.

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