Available on the FAQ page at: http://www.citiprogram.org

Welcome to the Inaugural Issue of the CITI Newsletter

The Newsletter will be published three times a year and will arrive via email.

Each issue of the Newsletter will cover a hot topic, introduce new modules, provide an update on new CITI developments, and respond to readers' questions via a "Let's Ask Susan" column. Please let us know of any suggestions you might have to make this a Newsletter one you will look forward to seeing when you open your email.

Inquiries about the CITI Program should be directed to the CITI Office at the University of Miami at 305 243-7970 or by email to citisupport@med.miami.edu

CITI: Then and Now

The Collaborative Institutional Training Initiative, first known as the Collaborative IRB Training Initiative and both known as CITI, has come a long way since its inception in June 2000. This on line training resource evolved in response to the Department of Health and Human Services requirement for human subjects training for researchers receiving federal funds. The project's founders Karen Hansen, Director, Institutional Review Office at the Fred Hutchinson Cancer Research Center, and Paul Braunschweiger, Director of the Office of Research, Education and Training at the University of Miami's Miller School of Medicine, got together and brainstormed this idea while attending a conference. As the idea blossomed into a more concrete project, they invited representatives from Albany Medical Center, Children's Hospital-Boston, Dartmouth College, University of Kentucky, University of Miami, Fred Hutchinson Cancer Research Center, the National Comprehensive Cancer Network, University of Nebraska, Group Health Cooperative and the University of Washington. These institutions and their representatives were invited to provide their expertise related to the content and context with regard to human subjects research ethics and regulations.

As of summer 2007, this novel idea has grown into an international web based resource for education and information relating to human subjects research and its regulations,

good clinical practices, responsible conduct of research, health information protections and now animal research. CITI now serves more than 600,000 people from more than 750 institutions.

The content of the original module, the "Basic Course" was developed by members of the group above and has been continually reviewed and revised twice yearly based on feedback and comments submitted by CITI users. The goal is to have the most accurate, relevant materials available for the research community. "Refresher" courses are now offered for the basic Biomedical and Social Science courses, these courses provide a brief but focused review of specific issues in the realm of human subject's research.

The increase in international collaboration and the need to understand the complex realm of U.S. regulatory requirements has led to the translation of CITI's human subjects modules into Spanish, Chinese, Portuguese, French and Arabic. Current work with ethicists and regulators from the Caribbean and South America will lead to more learning enhancements and exchanges of information about what is required of U.S. researchers wanting to conduct research in these locales.

CITI continues to work closely with its user groups to find ways to respond to the needs of the research community. This Newsletter is just an example of communications planned by CITI. The Newsletter will be sent three times a year to all CITI Administrators. We look to you for suggestions, ideas for stories, questions of general interest and voluntary articles.

The decade's long growth in international clinical trials has brought with it an unaddressed need for educational infrastructure in many languages to enable all researchers to learn the regulations and ethical standards of the United States as well as those of the host country.

CITI, building on its domestic outreach in human subject research education has entered the international educational arena through initiatives that leverage funding, experts, and partnerships across institutions and countries. The resulting educational collaborations and programs could not have been imagined in 2000 when CITI first launched as a distance learning format shared by the 10 founding domestic organizations.

Four of these international initiatives and their leaders are highlighted here.

1. **The Caribbean Research Ethics Initiative (CREI)**
    Leader: Anthony Mullings, MD
    Organization: University of the West Indies
    Research activity in the Caribbean is varied and involves research undertaken by government and private entities. CREI created the following goals:
    - address the research ethics education needs of the Caribbean research framework,

- sensitize the public and academics to issues of research ethics,
- strengthen opportunities and facilities for ethics training, and
- foster development of research ethics committees.

2. **CITI in Taiwan**
   Leader: Benjamin Kuo, MD
   Organization: Joint Institutional Review Board (JIRB), Taipei, Taiwan

   Dr. Kuo has been an active member of the CITI working group since 2005. He has translated content into traditional Chinese for utilization by the JIRB and research community. He is planning to launch a demonstration project where contract research organizations (CROs) in Taiwan would receive training through the use of CITI modules.

3. **CITI in Latin America**
   Leader: Sergio Litewka, MD
   Associate Professor Surgery,
   Organization: University of Miami

   Dr. Litewka, who also has an appointment in the University of Miami Ethics Program, is leading the development of a Spanish language CITI Program for Latin America. He has been instrumental in coordinating specific collaborations with research organizations and ethicists from Brazil and Chile who are utilizing and/or creating CITI training modules. The goals of these collaborative efforts are to:
   - create country-specific content that addresses the regulatory framework for clinical trials,
   - improve ethical components of health research,
   - promote international and respectful networking, and
   - provide context sensitive Spanish language materials and training.

4. **Multi-Language Public Access International Course in Human Subjects Basics**
   Leader: Karen Hansen
   Director, Institutional Review Office, Fred Hutchinson Cancer Research Center

   As research continues to expand across borders, the CITI international public access course site is a growing collection of public access human subjects education modules for researchers and IRB/Research Ethics Committees (REC). Two tracks of training are available that provide an overview of international research ethics issues, as well as general research ethics for US federally funded research.   NIH enhancement grants, international collaborators involved with CITI, and translators have combined resources to help make this platform available for public use at www.irbtraining.org .

The CITI Laboratory Animal Welfare Program

CITI is pleased to announce that the CITI Laboratory Animal Welfare Educational Program is now available for CITI Participating institutions. We are indebted to Dr. Michael Fallon at the Atlanta VA for making the "Lab Animal" content available to CITI and for helping to modify the functionality of the current software package to efficiently present the course materials.

The Program consists of 2 basic courses:

1. "Working with the IACUC"
2. "Essentials for IACUC Members"

And 15 Elective Courses:

1. Working with Amphibians in Research Settings
2. Working with Mice in Research Settings
3. Working with Rats in Research Settings
4. Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress
5. Working with Hamsters in Research Settings
6. Working with Gerbils in Research Settings
7. Working with Guinea Pigs in Research Settings
8. Working with Rabbits in Research Settings
9. Working with Cats in Research Settings
10. Working with Cats in Research - Refresher Course
11. Working with Dogs in Research Settings
12. Working with the Laboratory Dog CD-ROM: Basic and Advanced Lessons
13. Working with Swine in Research Settings
14. Working With Non-Human Primates in Research Settings
15. Streaming Video - Working Safely with Nonhuman Primates

Your organization can develop a specific curriculum to fit the needs of specific investigator groups. For example, you could design a curriculum for investigators who use mice in their work to include:

- "Working with the IACUC"
- "Working with Mice in Research Settings"
- "Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress"

In addition, you can develop your own modules or courses to be presented to your investigators on the CITI Software platform. The software will also permit us to program a Refresher or Re-certification curriculum at an interval (e.g., 1, 2, 3, 4 or 5 yrs) that you determine. The also software is designed to send out email alerts to investigators prior to the expiration of the certificate.

Other features include:

- An attractive presentation paradigm that is simple for the learner to use.
- The ability to set the passing score.

- E-mail completion report notifications to IACUC coordinator.
- Training data downloads
- Direct connections to tie the CITI database to your information management system.
- The ability of learners to register with multiple institutions.
- Training records archives.

Direction for the Lab Animal Welfare Program is provided by the Lab Animal Welfare Working Group under the leadership of long time University of Nebraska IACUC Chair, Michael Mann, Ph.D. Dr. Mann and the 12 member working group will meet for the first time in Seattle in October to review the current content, discuss immediate needs, new content initiatives and future directions. The Program is managed by the CITI Office at the University of Miami.

For more information on the CITI Lab Animal Program follow the link to the **Announcements and FAQ** at www.citiprogram.org . If you need more information or would like to request a set-up, don't hesitate to call Eddie or Marcos at 305 243-7970. To review a CITI Lab Animal Welfare "DEMO" course:

- Login to the CITI Program.
- Use the link on the learner menu to "Affiliate With Another Institution."
- Under participating institutions choose "CITI Laboratory Animal Welfare Demonstration Course."

We are confident that you will find this course a valuable component to your training program. The best part is that it is available to all Participating institutions at no additional fee.

Let's Ask Susan…

Hey Susan, I have a new researcher who took CITI at her last institution. We'd like to incorporate her CITI coursework into our system. Can we do this?

Yes, your researcher can log into CITI using her old log in and email and "re-affiliate" herself with your institution. This allows her to access information about the courses that she has completed and share that information with you.

Hey Susan, We will now require our research community to complete continuing education and training through the CITI "refresher course." How will our researchers and study staff know when they are due for the refresher course?

Contact the CITI help desk to establish your training requirements. They can log this information into the system and create an automatic reminder system for your research community members as well as allowing you to search the database to determine who is due for the refresher course.

Hey Susan, I'm new to CITI. How do I navigate CITI to reach my desired destination?

Learners may find it challenging to navigate through the many modules now available in CITI, e.g., having to register in different learner groups to get to specific modules. Typically institutions have a point person who establishes the requirements for learner groups and to whom learners turn for help. When the problem cannot be resolved at an institutional level, please email the CITI office citisupport@med.miami.edu or call 305 243-7970. Also, please notify the CITI Central Office with any suggestions you have to assist us in making CITI a user-friendly program.

Hey Susan, We heard that there is a Good Clinical Practice training program available through CITI. How can we review this program?

Institutions seeking a resource for Good Clinical Practice (GCP) training may access a demo of the GCP modules by going to the PRIM&R web site or may contact the CITI Help Desk to set up a GCP trial. If your institution chooses to use the GCP modules, you may contact CITI Help Desk to set up an optional GCP learner group and provide you with a direct link.

Hey Susan, We heard that CITI also has a course in the Responsible Conduct of Research (RCR). How can we review this program?

Institutions or course instructors who want to incorporate RCR education for students, faculty and staff into their research education programs should review the public access RCR materials available at the CITI course site. As with all CITI Courses, the RCR curriculum can be customized according to discipline (e.g., Biomedical, Social Sciences, Physical Sciences and the Humanities) to meet your needs.

Hey Susan, What happens to the questions, comments and suggestions that CITI receives from learners?

The CITI office monitors all comments received regarding the Biomedical, GCP and optional modules. Comments fall into three general categories: 1) a coding/software glitch (corrected within the CITI office), 2) general comments, either praise or criticism, and 3) specific comments about answer choices and/or facts in the main text.

All comments are reviewed and responded to. Coding and software glitches are attended to as quickly as possible. Comments regarding general praise or criticism are captured and shared with the CITI Faculty. Specific comments about answer choices and/or fact in the main text are sent to CITI Coordinating Feedback Editors who work with authors to review feedback from learners and revise the module content as appropriate. When a learner offers specific information, CITI responds to their comments and lets them know how the issue was or will be resolved.

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How to Sign Up/Off Newsletter

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