

STEP BY STEP INSTRUCTIONS TO BEGIN YOUR TRAINING (You must register first at <http://www.citiprogram.org> )

1. Go to the training site at <http://www.courses.miami.edu/bin/common/courses.pl> (Note that the last two letters are "p" as in pink and "l" as in "lemon.")
2. Enter your USERNAME and PASSWORD (both are case sensitive)
3. You will enter the CITI training site at a page listing the courses that you have registered for.
4. Click on the link to the course
5. On the COURSE INFORMATION Page, you will also see a links to information about the site.
6. Begin your training by clicking on the Link to "Begin the COURSE. Follow the directions to complete the course.

#### ADDITIONAL INFORMATION TO HELP YOU COMPLETE YOUR TRAINING

7. THE PURPOSE of the CITI was to devise, implement and administer a self directed web based educational program in the ethics of human subjects' research and IRB procedures. The program is designed to meet or exceed the NIH requirements of training in human subjects' protection, yet be flexible enough to meet all institutional and/or state requirements.
8. THE UNIVERSITY OF UTAH. This course in human subjects' protection and bioethics is designed specifically for all personnel that have a significant involvement in the planning, conduct and analysis of any scientific activity that employs human beings as research subjects. This course is specifically designed to meet the June 2000 PHS Policy mandate that all key personnel involved in PHS funded human subjects research, must have formal instruction in human subjects protection.
9. THE LEARNING OBJECTIVES are:
  - a) to provide the UNIVERSITY OF UTAH with an understanding of the historical perspectives, ethical principals and federal regulations associate with the conduct of research with human subjects.
  - b) to provide the UNIVERSITY OF UTAH with a clear understanding of what constitutes informed consent and how it must be applied in human subjects research.
  - c) to provide the UNIVERSITY OF UTAH with basic information on the regulations and policies governing research with investigational drugs, biologicals and devices.
  - d) to provide the UNIVERSITY OF UTAH with a clear understanding of the findings of The International Commission on Harminazation and how these findings affect the conduct of research with human subjects around the world.
  - e) to provide the UNIVERSITY OF UTAH with an understanding of the special considerations that must be addressed when "Vulnerable Populations" such prisoners, minors, pregnant women and fetuses in utero are used in research activities.
  - f) to provide the UNIVERSITY OF UTAH with new insights into the concept of Group Harms in vulnerable populations and the use of Community Consultation to prevent injury to special social structures.
  - g) to provide the UNIVERSITY OF UTAH with a clear understanding of the ethical issues and federal regulations in force during the conduct of Social / Behavioral Research, Records Based Research and Genetics Research with human subjects.
  - h) to provide the UNIVERSITY OF UTAH with a clear understanding of the special procedural and regulatory policies for human subjects research at VA research facilities.
  - i) to provide the UNIVERSITY OF UTAH with new information on late breaking topics that may affect the use of human subjects in research. The intent is to provide the user with the latest guidance from regulatory agencies and to provide timely information on new human subjects' issues.
10. GENERAL STRUCTURE OF THE TRAINING MODULE. To successfully complete your human subjects research instruction you are required to:

\*\*complete all 14 Modules of the Biomedical Course unless your institution gives you other instructions.

or

\*\*complete all 11 Modules of the Social / Behavioral Course unless your institution gives you other instructions. If you do not know which course you are expected to complete, contact your IRB training Coordinator by dialing (801) 581-3655.

\*\*complete the quizzes as you complete each Module.

\*\*complete at least one unit of Instruction specific for your home institution.

\*\*submit a confirmation form to your IRB training coordinator

\*\*complete a survey about the course (optional)

11. COMPLETE ALL MODULES. To successfully complete this training module, you must review all assigned modules and complete 1 quiz for each part. Some institutions have given their employees special instructions regarding which modules to complete. MAKE SURE YOU CHECK THE LINK TO SEE IF YOUR INSTITUTION HAS SPECIAL INSTRUCTIONS FOR YOU.

You do not have to complete all of the modules at one time. In fact, it is preferable to do several at one sitting and then come back later to complete unfinished modules. The software will keep track of your progress and keep track of the quizzes that you have completed. When you re-enter the site there is a link to check which quizzes you have completed.

Links to print out the course content are also provided for your convenience.

12. QUIZZES: There is one quiz for each of the Core Modules. "HOT TOPICS" has no quiz. Your institution may however, have an additional quiz for you to complete after you finish the HOT TOPICS Module. You must finish all assigned quizzes to complete the course. You may re-enter a quiz multiple times to complete it. The software will store your most recent attempt.

- I If you have problems with the software you may call CITI Support at (305) 243-7970 for assistance.

Quiz scores will be tabulated by the software and used by the training coordinators to determine if you have completed all of the modules and satisfied institutional requirements. Quiz scores will be confidentially maintained by the software. Your raw scores will be provided to your IRB training coordinator only upon request. The aggregate quiz scores may be used (without identifiers) by the developers to evaluate the curriculum and its presentation. CITI key trainers may have access to the CITI software to reset quizzes and remedy registration problems (e.g., forgotten passwords, and usernames). This is done so that CITI can provide a timely response to any problems you might have. All key trainers who are provided with access to the CITI site software have signed a pledge of confidentiality and nondisclosure with regard to the CITI training data.

13. SOFTWARE REQUIREMENTS: You will need a Word Processor program such as MS Word and Adobe Acrobat Reader. You should also use a Browser that supports Java script (i.e., MS Explorer ver 5.0 or higher or Netscape Navigator version 6.2 or higher). Links to obtain free copies of the latest versions of the browsers are provided.

14. NAVIGATION THROUGH THE TRAINING MODULES: Start with Module #1 by clicking on the "Begin the Course" link. Hyperlinks will help you navigate from one Module to the next. Your institution may excuse you from some modules. Make sure you view the link to "institutional requirements"

- a) Complete the quizzes as you complete each required module. After you complete the last module, follow the links to the HOT TOPICS page. After you review this material you will be directed to your Institution's Page.

- b) Your IRB may provide additional information that is specific for your institution. You will then complete the course by submitting an email form to your training coordinator. Your training coordinator will review your records for completeness and according to your institutional policy. Your IRB will then send you a letter or certificate of completion.

- c) Although Hyperlinks are provided to guide you smoothly through the training module, the NAVIGATION BUTTONS in the left margin will always be in view and may be helpful as you become more familiar with the Blackboard 5.5 Distance Learning Software. For example, the COURSE INFORMATION button will always bring you back to the Welcome Page.

- d) AN IMPORTANT NOTE TO ALL REGISTRANTS REFERED THROUGH THE NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN). If you registered for the CITI course through the NCCN web site and have a username that starts with NCCN, your completion forms will be found on the NCCN Institutional page. When you finish the last quiz in the program you will be instructed to go to the NCCN page to submit the form to your institutional trainer. The institutional page is also accessible from the Welcome page of the Course web site.

15. **HYPERLINKS:** You are also invited to visit the **EXTERNAL LINKS** section of the training site where you will find **LINKS** to several institutional web sites as well as **LINKS** to the sites of professional and regulatory organizations.
16. If at any time you get lost, you can come back to the **WELCOME** page and the **CORE TRAINING** entry point by clicking on the green "Course Information" button in the left margin.
17. **HELP!!!** If you have problem moving through the software or course content you can call your IRB office for assistance. The Name and phone number of your institution's IRB staff member familiar with this training site is found by clicking on the button labeled **STAFF INFORMATION**. Also click on the "contact your training coordinator link" (**WELCOME PAGE**) to send your IRB professional an email message.