Human Subjects Protection Training

To assure that all clinical researchers understand their responsibility to protect the welfare of their research subjects, Hawai'i Pacific Health (HPH) requires that researchers be "certified" in human subjects protection before conducting research. All clinical researchers must be certified in order to do clinical research at HPH. Everyone who is involved in designing a clinical study, has contact with research subjects or their data, or is responsible for analyzing data and developing study results should be certified. This would include, investigators, research coordinators and other research staff, study biostatisticians, and study data managers.

Certification can be obtained by completing the Collaborative Institutional Training Initiative (CITI) program. Researchers must provide certification of completion with any research proposal submitted. The instructions for completing the CITI training course are as follows.

HOW TO USE THE CITI TRAINING COURSE

Website: http://www.citiprogram.org

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How to Register and Login

Step 1: Open your Internet Program and enter this address: <u>http://www.citiprogram.org/</u>. Click on "**Register Here**".

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Forgot username or password? How do I use the new Lab Animal Course? See how your institution can become a CIII	Welcome CITI Login and Registration Page Image: The CITI Program is a subscription service providing ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.	
participant	The CITI course is a protected site. If you are a new learner at a participating organization you must register to create yown username and password and gain access to the site.	our
	 The CITI Program offers Public Access Courses to individuals and research organizations. Take the: Public Access Course in <u>Responsible Conduct of Research (RCR)</u> (includes access to the course, "Essentials for IACUC Members") Public Access Course in <u>Health Information Privacy and Security Course</u> Public Access <u>CITI International Course</u> Site Laboratory Animal Welfare (under construction, a complete series of courses is coming in June 2007) Notice: The CITI Program often experiences very heavy usage. To ensure that all users enjoy rapid response times, access is temporarily limited to 800 concurrent users. As learners log others will be permitted to log on. There are currently 47 users logged in to the site. Notice: The CITI Course site is best viewed with Microsoft Internet Explorer ver. 5.0 or later or Firefox ver. 1.5 or later. 	off
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Step 2: Select "Hawaii Pacific Health Research Institute" in the "Participating Institutions" drop down box and click on the SUBMIT button.

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Select your institution or organization	
Choose your institution from the appropriate dropdown menu then click SUBMIT . If you are affiliated with more than one in additional institutions after providing the information required.	stitution, you will be able to select
Participating Institutions: Hawaii Pacific Health Research Institute	
Veterans Anairs.	
Department of Energy:	
HIV/AIDS Network Coordination (HANC):	
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Step 3: Create a user name and password.

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CITI Course in The Pro	tection of Human Research Subjects		
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Username: Jesting			
Your pass and should consist of 8 to 12 characters are allowed. Your passworth	characters. Letters and a most are the only acceptable characters. No spaces or other not case sensitive, "A12B34CD" is the same as "a12b34cd".		
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Step 4: Enter your name and email address.

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CITI Collaborative Institutional Training Initiative		-
Enter your first name, last name, and preferred email address in the fields below.		
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Last Name:		
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Step 5: Input your Information. Fill in all the necessary information. (* Indicates a necessary field. The field must not be left blank or your registration will not be processed.)

Once you are done be sure to double check your information before clicking on the Submit information button.

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	May we re-contact you to complete a course survey?	CITI conducts new research surveys every 6-8 months to determine how learners use the course site and whether the Federal educational mandate is producing the intended result. We would like you to help us in the program evaluation.		
		Enter YES if we may contact you sometime in the future to		

Step 6: Group Selection. Check Appropriate Group and click on the Submit button. In most cases you will need to select Group 1.

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	CITI Course in The Protection of Human Research Subjects		
	Select Groups - Hawaii Pacific Health Research Institute		
	Question 1 Select the group appropriate to your research activities.		
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	C Group 2.		
	This course is suitable for Investigtors and staff conducting SOCIAL / HUMANISTIC / BEHAVIORAL RESEARCH with human subjects. The VA module must be completed if you plan to work with subjects at a VA facility.	r)	
	Question 2 Select the group for which you have previously completed an institutionally approved Basic Course in the Protection of Human Research Subjects.	5	
	Question 2 Select the group for which you have previously completed an institutionally approved Basic Course in the Protection of Human Research Subjects. Choose one answer		
	Question 2 Select the group for which you have previously completed an institutionally approved Basic Course in the Protection of Human Research Subjects. Choose one answer C Group 1		
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Step 7: Select your institution or organization.

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Select your institution or organization		_
You have registered with the following institution(s):		
Hawaii Pacific Health Research Institute		
Also a VA Member?		
Remember to affiliate yourself with your VA Medical Center as well!! Click yes below to do it		
Do you need to take training for more than one institution?		
Yes No		
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The Basic Course

Step 1: All users must complete the Basic Course. Click on "Basic Course".

Click on the grade book link to enter the course.

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	 This is the email address we have for you: ninam@kapiolani.org. If this is not You are affiliated with 1 participating institution(s) on the CITI website. You we track your progress in meeting the institution's coursework requirements (see 	t correct, please <u>edit or change your address</u> now. ill have at least one grade book per institution to e below).	
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Step 2: Each module must be completed in order to proceed to the next module. To begin the modules, please click on "<u>Introduction</u>". You do not have to complete all the modules in one session.

<u>For returning users</u>: Click on the next module that is <u>red and underlined</u> that you need to complete.

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Take the next required module, Introduction.			
Required Modules	Date Score		
Introduction (ID 57)	Incomplete		
History and Ethical Principles(ID: 498)	Incomplete		
Basic Institutional Review Board (IRB) Regulations and Review Process₀c: ₂)	Incomplete		
Informed Consent(ID: 3)	Incomplete		
Social and Behavioral Research for Biomedical Researchers(D: 4)	Incomplete		
Records-Based Research(ID: 5)	Incomplete		
Genetic Research in Human Populations(ID: 6)	Incomplete		
Research With Protected Populations - Vulnerable Subjects: An Overview(ID: 7)	Incomplete		
Vulnerable Subjects - Research with Prisoners(ID: 8)	Incomplete		
Vulnerable Subjects - Research Involving Minors(ID: 9)	Incomplete		
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero((D: 10)	Incomplete		
Group Harms: Research With Culturally or Medically Vulnerable Groups(0: 11)	Incomplete		
FDA-Regulated Research(ID: 12)	Incomplete		
HIPAA and Human Subjects Research(ID: 14)	Incomplete		
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	Incomplete		
Hawaii Pacific Health Research Institute(ID: 665)	Incomplete		

Step 3: Module.

When you click on the "<u>Introduction</u>" module or future modules, below is what you will see. Each module contains information, references, and links to supporting regulations, important documentation, and a quiz at the end of each module.

Read and review the information in the module before you take the short quiz at the end.



Step 4: The Quizzes

Once you have entered the Quiz you can not go back. If you go back or exit the Quiz it may affect your overall score and you may need to re-take the quiz.

Answer each question and when complete click on "Submit Exam" at the bottom of the screen.

<	Submit Exam
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Step 5: The Results:

Once the Quiz is submitted you will receive your results in a matter of seconds (depending on your internet connection).

Step 6: At the end of each Quiz you will be given an option:

If you are ready to continue on to the next module click on "Go to the next module".

If you would like to go to the gradebook for this curriculum click on "Go to the gradebook for this curriculum".

If you would like to go to the main menu click on "Main Menu".

If you would like to view this module again click on "View this module again".

If you would like to submit a comment about this exam click on "Submit a comment about this exam".

Go to the next module, Basic Institutional Review Board (IRB) Regulations and Review Process

Go to the gradebook for this curriculum

Go to the Main Menu

View this module again

Submit a comment about this exam

Step 7: Repeat Steps 2 - 6 until you have completed all modules. You do not have to complete all the modules at one sitting. If you are taking a quiz and would like to quit please complete the quiz before you quit the module.

Completing the Course

Step 1: Once all modules are complete, return to the main menu and select "View course completion history for *Hawaii Pacific Health Research Institute* and print completion certificates".



Step 2: Select "Print Completion Report" for the course that you would like to print a report for.

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Step 3: Print your completion report for your records. An electronic copy will automatically be sent to the Hawaii Pacific Health Research Institute.

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	Learner: howto guide (username: howtoguide)		
	Institution: Hawaii Pacific Health Research Institute		
	Contact Department IRB		
	Information: Phone: 8085224581 Email: ninam@kapiolani.org		
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Should you need help please contact Christine Nelson at 535-7215 or Christine.Nelson@kapiolani.org