

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

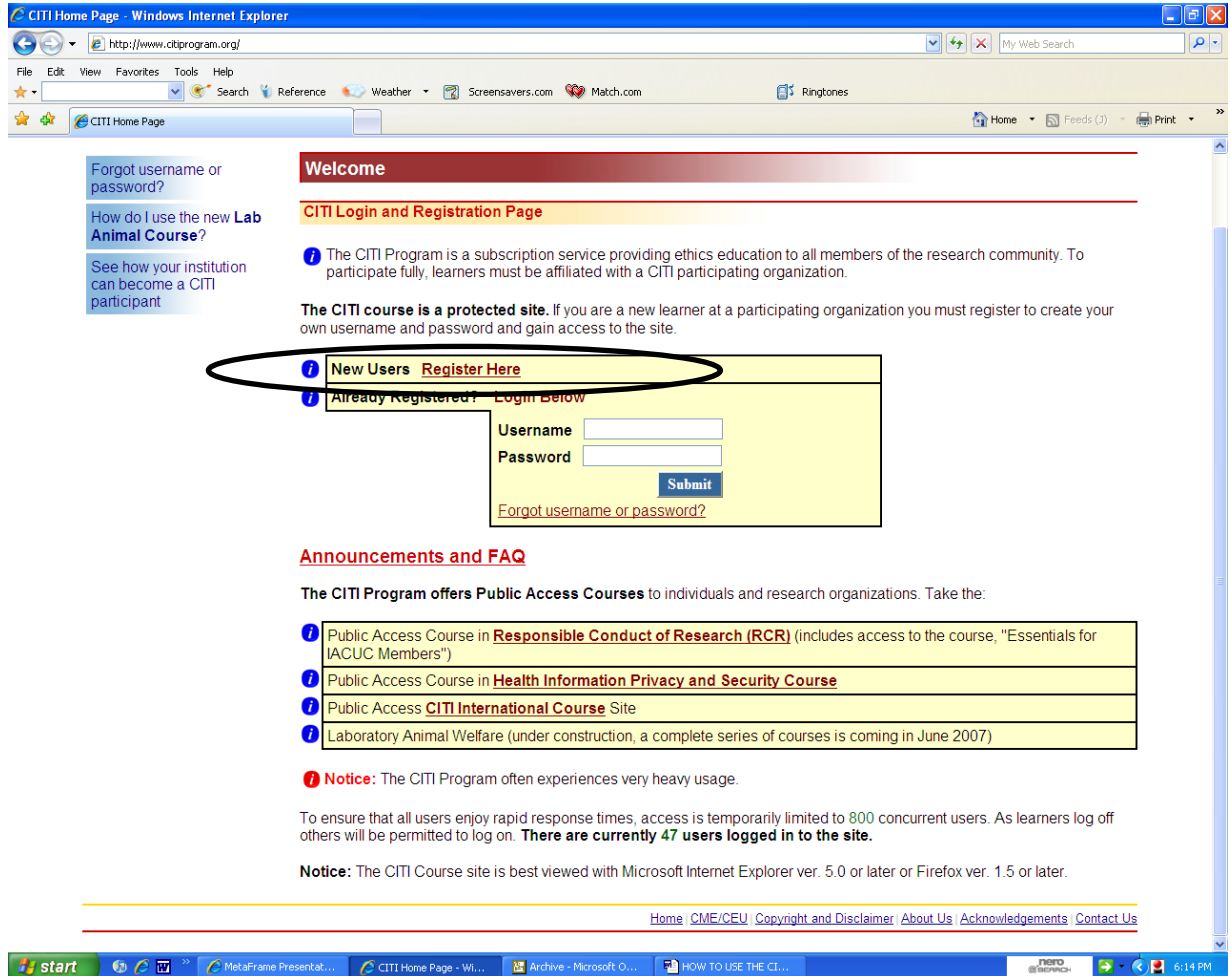
Website: <http://www.citiprogram.org>

Table of Contents:

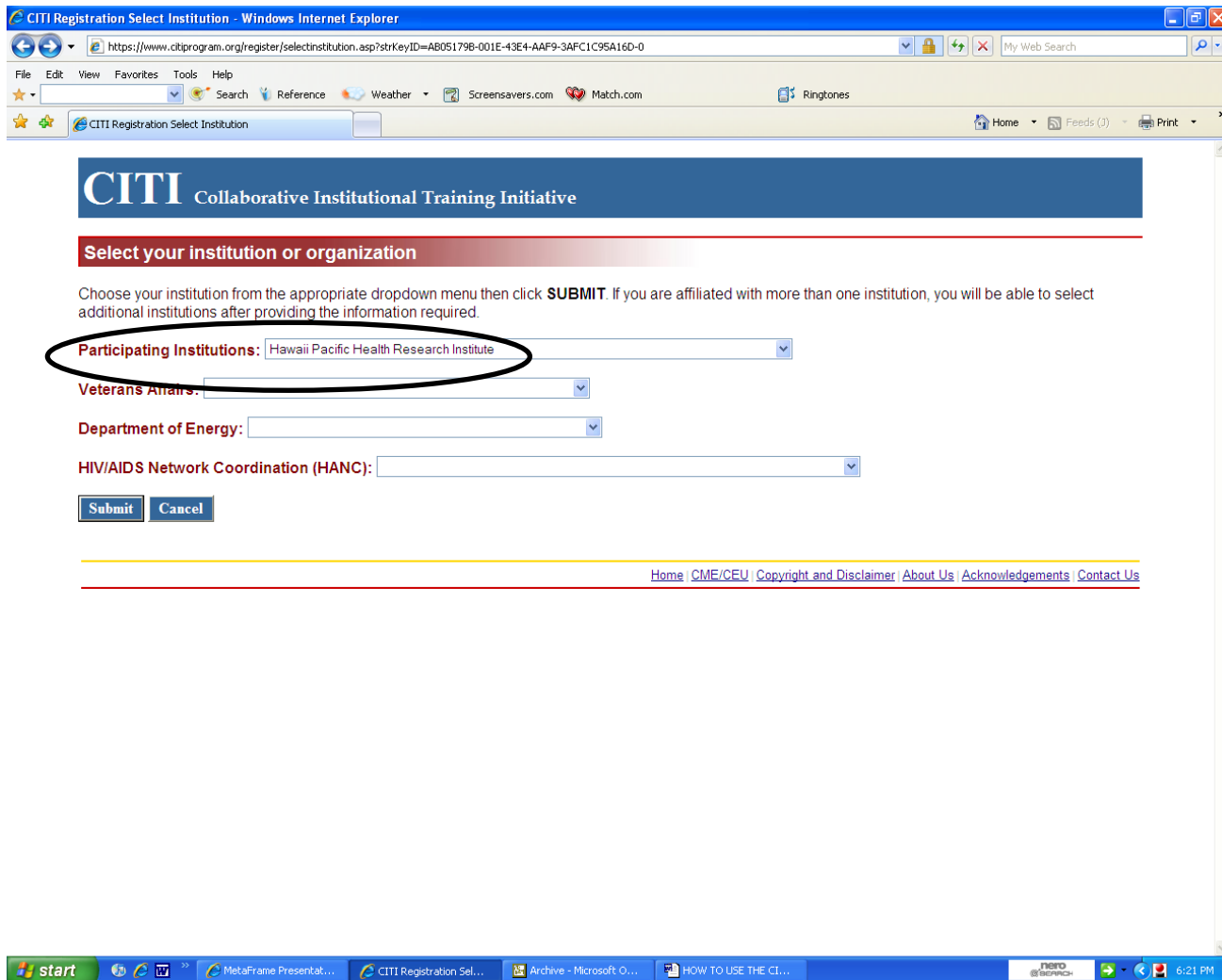
1	Introduction
2	How to Use the CITI Training Course
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How to Register and Login

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



Step 2: Select “Hawaii Pacific Health Research Institute” in the “Participating Institutions” drop down box and click on the SUBMIT button.



Step 3: Create a user name and password.

CITI Course in The Protection of Human Research Subjects

Select Your Username and Password

Your username should consist of 4 to 50 characters. Acceptable characters include letters, numbers, and the symbols "@", ".", and "-". No special or control characters are allowed. Your username is **not case sensitive**. "A12B34CD" is the same as "a12b34cd".

Username:

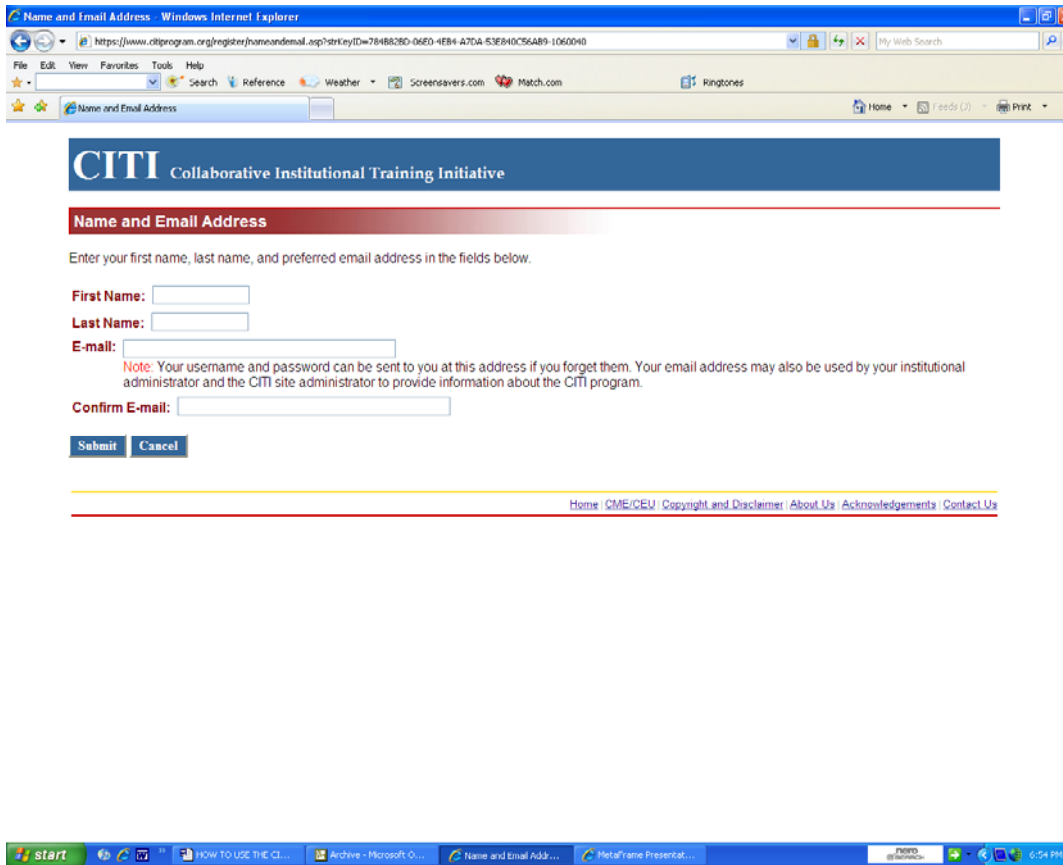
Your password should consist of 8 to 12 characters. Letters and numbers are the only acceptable characters. No spaces or other characters are allowed. Your password is **not case sensitive**. "A12B34CD" is the same as "a12b34cd".

Password:

Verify Password:

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Step 4: Enter your name and email address.



The screenshot shows a Windows Internet Explorer browser window with the following details:

- Browser Title:** Name and Email Address - Windows Internet Explorer
- Address Bar:** <https://www.citi-program.org/register/nameandemail.asp?strKeyID=7848826D-06E0-4EB4-A7DA-53F840C5AAB9-1060040>
- Page Header:** CITI Collaborative Institutional Training Initiative
- Section Header:** Name and Email Address
- Text:** Enter your first name, last name, and preferred email address in the fields below.
- Form Fields:**
 - First Name:
 - Last Name:
 - E-mail:
 - Confirm E-mail:
- Note:** Your username and password can be sent to you at this address if you forget them. Your email address may also be used by your institutional administrator and the CITI site administrator to provide information about the CITI program.
- Buttons:** Submit, Cancel
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The Windows taskbar at the bottom shows the Start button, several open applications (including 'HOW TO USE THE CI...', 'Archive - Microsoft O...', 'Name and Email Addr...', and 'MetaFrame Presentat...'), and the system tray with the time 6:54 PM.

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.

The screenshot shows a web browser window titled "CITI Member Information - Microsoft Internet Explorer". The address bar shows the URL: <https://www.citiprogram.org/register/memberInformation.asp?siteKeyID=40029929-770F-4891-9866-FC0C402426FF-076671>. The page header includes the CITI logo and the text "CITI Course in The Protection of Human Research Subjects". Below the header is a red banner with the text "Member Information". The main content area contains a form with the following fields and labels:

- Gender: [Dropdown menu]
- Highest degree: [Dropdown menu]
- Employee Number: [Text input field]
- Department: [Text input field]
- What is your role in research?: [Dropdown menu]
- Address Field 1: [Text input field]
- Address Field 2: [Text input field]
- Address Field 3: [Text input field]
- City: [Text input field]
- State: [Text input field]
- Zip/Postal Code: [Text input field]
- Country: [Text input field]
- Office Phone: [Text input field]
- Home Phone: [Text input field]
- May we re-contact you to complete a course survey?: [Dropdown menu]

Below the form, there is a paragraph of text: "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." and a note: "Enter YES if we may contact you sometime in the future to request your participation in a survey study. Enter NO if you".

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

The screenshot shows a web browser window titled "Select Groups - Microsoft Internet Explorer". The address bar shows the URL: <https://www.citiprogram.org/register/selectgroups.asp?siteKeyID=06400C2D-669A-4E23-9C39-7367C0F44CE1-076671>. The page header includes the CITI logo and the text "CITI Course in The Protection of Human Research Subjects". Below the header is a red banner with the text "Select Groups - Hawaii Pacific Health Research Institute". The main content area contains two questions:

Question 1 Select the group appropriate to your research activities.

Choose one answer

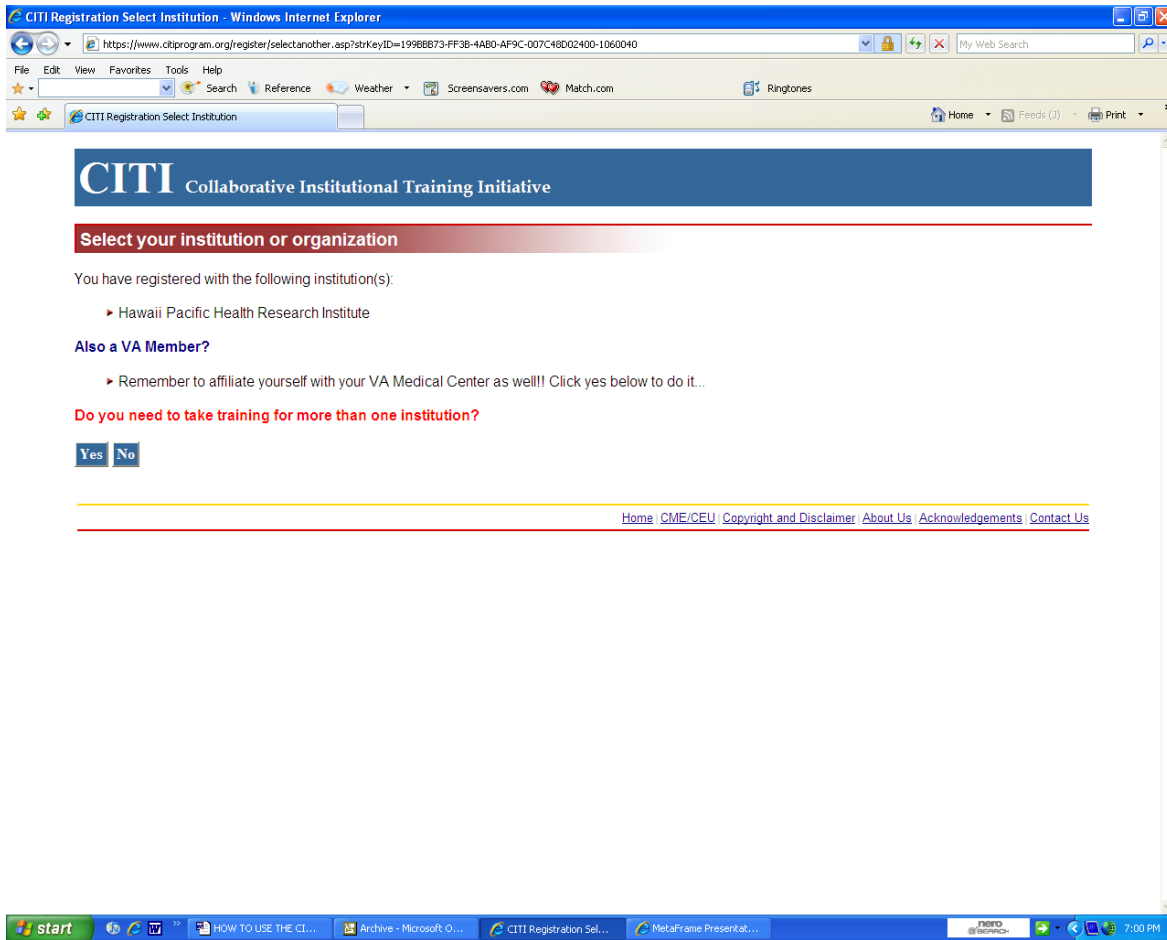
- Group 1: This course is suitable for investigators and staff conducting BIOMEDICAL RESEARCH with human subjects.
- Group 2: This course is suitable for Investigators and staff conducting SOCIAL / HUMANISTIC / BEHAVIORAL RESEARCH with human subjects. The VA module must be completed if you plan to work with subjects at a VA facility.

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

- Group 1: This course is suitable for investigators and staff conducting BIOMEDICAL RESEARCH with human subjects.
- Group 2: This course is suitable for Investigators 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.
- I have not previously completed an approved Basic Course.

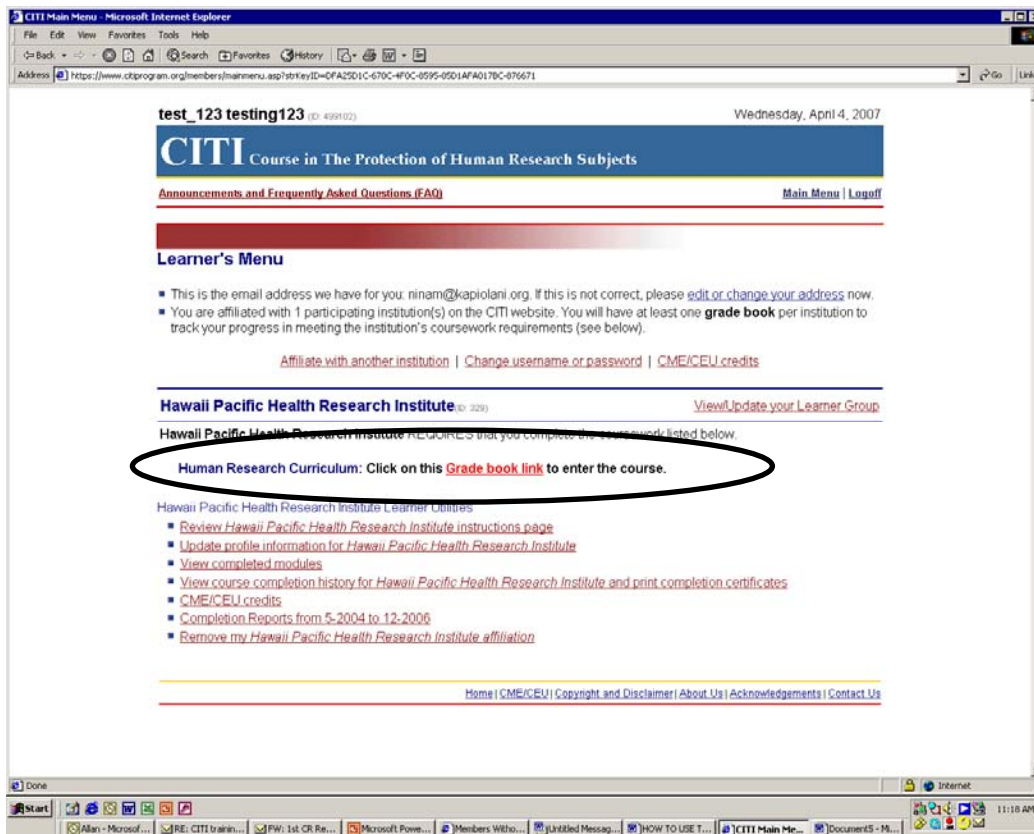
Step 7: Select your institution or organization.



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.



Step 2: Each module must be completed in order to proceed to the next module. To begin the modules, please click on "**Introduction**". You do not have to complete all the modules in one session.

For returning users: Click on the next module that is **red and underlined** that you need to complete.

test_123 testing123 (ID: 499102) Wednesday, April 4, 2007

CITI Course in The Protection of Human Research Subjects

[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu](#) [Logoff](#)

Human Research Grade Book

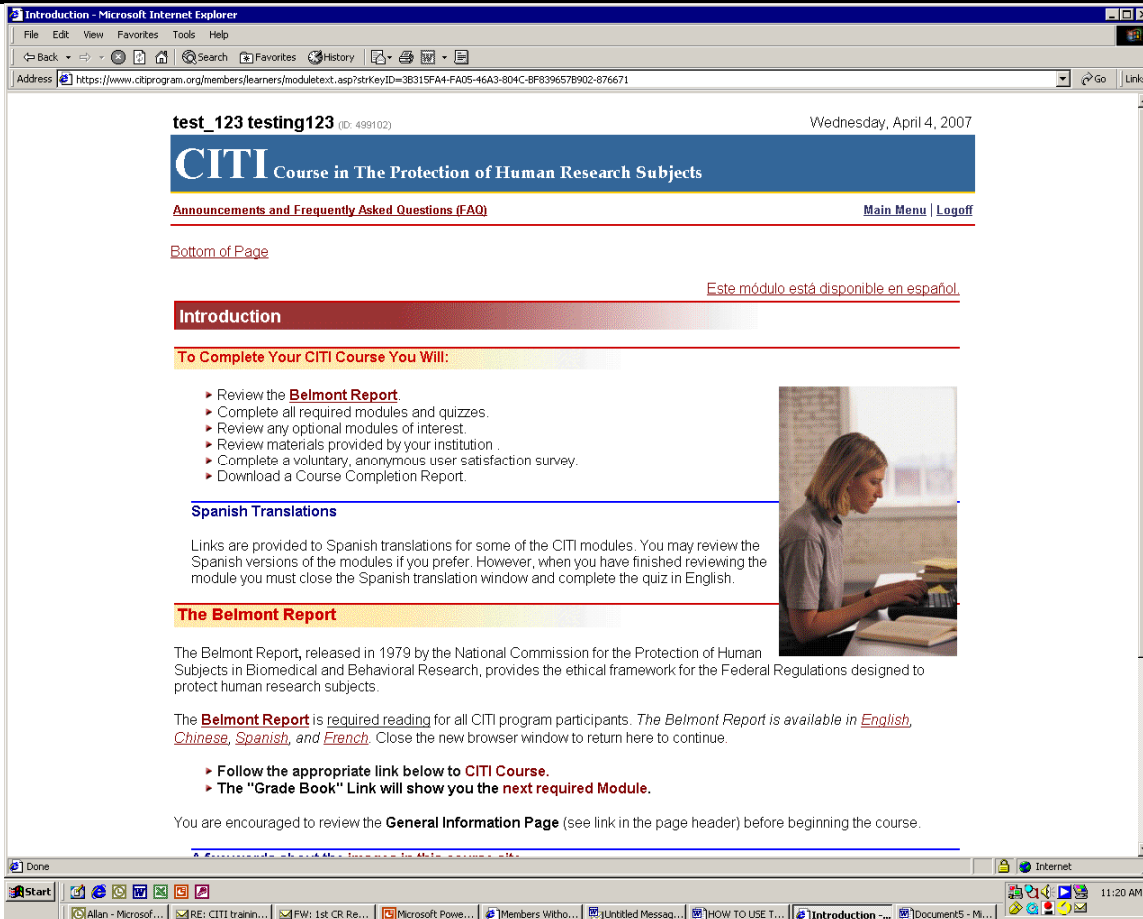
[Take the next required module, Introduction.](#)

Required Modules	Date	Score
<u>Introduction</u> (ID: 97)		Incomplete
History and Ethical Principles (ID: 496)		Incomplete
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)		Incomplete
Informed Consent (ID: 3)		Incomplete
Social and Behavioral Research for Biomedical Researchers (ID: 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 (ID: 10)		Incomplete
Group Harms: Research With Culturally or Medically Vulnerable Groups (ID: 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: 406)		Incomplete
Hawaii Pacific Health Research Institute (ID: 665)		Incomplete

Step 3: Module.

When you click on the “**Introduction**” 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.



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”.

The screenshot shows the CITI Main Menu website in Microsoft Internet Explorer. The browser title is "CITI Main Menu - Microsoft Internet Explorer". The address bar shows the URL: <https://www.citiprogram.org/members/mainmenu.asp?strKeyID=11E40A79-FB9F-42F7-A8B7-F596CSA0FEFD-1064098>. The page content includes:

- Page title: **howto guide** (ID: 612427) and date: Monday, June 18, 2007.
- Header: **CITI Collaborative Institutional Training Initiative**.
- Navigation: [Announcements and Frequently Asked Questions \(FAQ\)](#) and [Main Menu | Logoff](#).
- Section: **Learner's Menu**.
- Text: "This is the email address we have for you: ninam@kapiolani.org. If this is not correct, please [edit or change your address](#) now." and "You are affiliated with 1 participating institution(s) on the CITI website. You will have at least one **grade book** per institution to track your progress in meeting the institution's coursework requirements (see below)."
- Links: [Affiliate with another institution](#), [Change username or password](#), [CME/CEU credits](#).
- Section: **Hawaii Pacific Health Research Institute** (ID: 329) with a link [Add a course or update your Learner Group](#).
- Text: "You have completed the following coursework for Hawaii Pacific Health Research Institute. If you would like to take additional modules in one of the curricula, click on a **green link** below. To print a completion report you earned or to find out information about receiving CME/CEU credits, click on the appropriate link in the list of Learner Utilities for this institution."
- Section: **Human Research Curriculum: Review Completed and Optional Modules** (ID: 4300).
- Section: **Hawaii Pacific Health Research Institute Learner Utilities**.
- List of links:
 - [Review Hawaii Pacific Health Research Institute instructions page](#)
 - [Update profile information for Hawaii Pacific Health Research Institute](#)
 - [View completed modules](#)
 - [View course completion history for Hawaii Pacific Health Research Institute and print completion certificates](#) (circled in black)
 - [CME/CEU credits](#)
 - [Completion Reports from 5-2004 to 12-2006](#)
 - [Remove my Hawaii Pacific Health Research Institute affiliation](#)
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Step 2: Select “Print Completion Report” for the course that you would like to print a report for.

Course Completion History - Microsoft Internet Explorer

Address: <https://www.citiprogram.org/members/learners/curriculumreport.asp?strKeyID=861FA0FE-C926-4C68-8F51-CAE6990C174B-1064098>

howto guide (ID: 612427) Monday, June 18, 2007

CITI Collaborative Institutional Training Initiative

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Course Completion History

Learner: howto guide
Institution: Hawaii Pacific Health Research Institute
Human Research Curriculum (ID: 4300)
Group 1. (ID: 1296) :

This course is suitable for investigators and staff conducting BIOMEDICAL RESEARCH with human subjects.

Stage	Ref #	Start Date	Required Modules	Elective Modules	Completion Date	Expiration Date	Modules Completed	Print CB
1. Basic Course	1085041	06/17/07	Completed	None Required	06/18/07	06/18/09	Modules Completed	Print Completion Report

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Taskbar: Start, Internet, Microsoft Outlook, HOW TO USE THE CITI T..., 2 Reminders, HP IRB Application Form..., Course Completion His...

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

CITI Course in The Protection of Human Research Subjects

Human Research Curriculum Completion Report
Printed on Monday, June 18, 2007

Learner: howto guide (username: howtoguide)
Institution: Hawaii Pacific Health Research Institute
Contact Department: IRB
Information: Phone: 8085224581
 Email: ninam@kapiolani.org

Group 1.:

This course is suitable for investigators and staff conducting BIOMEDICAL RESEARCH with human subjects.

Stage 1. Basic Course Passed on 06/18/07 (Ref # 1085041)

Required Modules	Date completed
Introduction	06/17/07
History and Ethical Principles	06/17/07
Basic Institutional Review Board (IRB) Regulations and Review Process	06/18/07
Informed Consent	06/18/07
Social and Behavioral Research for Biomedical Researchers	06/18/07
Records-Based Research	06/18/07
Genetic Research in Human Populations	06/18/07
Research With Protected Populations - Vulnerable Subjects: An Overview	06/18/07
Vulnerable Subjects - Research with Prisoners	06/18/07
Vulnerable Subjects - Research Involving Minors	06/18/07
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	06/18/07
Group Harms: Research With Culturally or Medically Vulnerable Groups	06/18/07
FDA-Regulated Research	06/18/07
HIPAA and Human Subjects Research	06/18/07
Conflicts of Interest in Research Involving Human Subjects	06/18/07
Hawaii Pacific Health Research Institute	06/18/07

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Selected information and

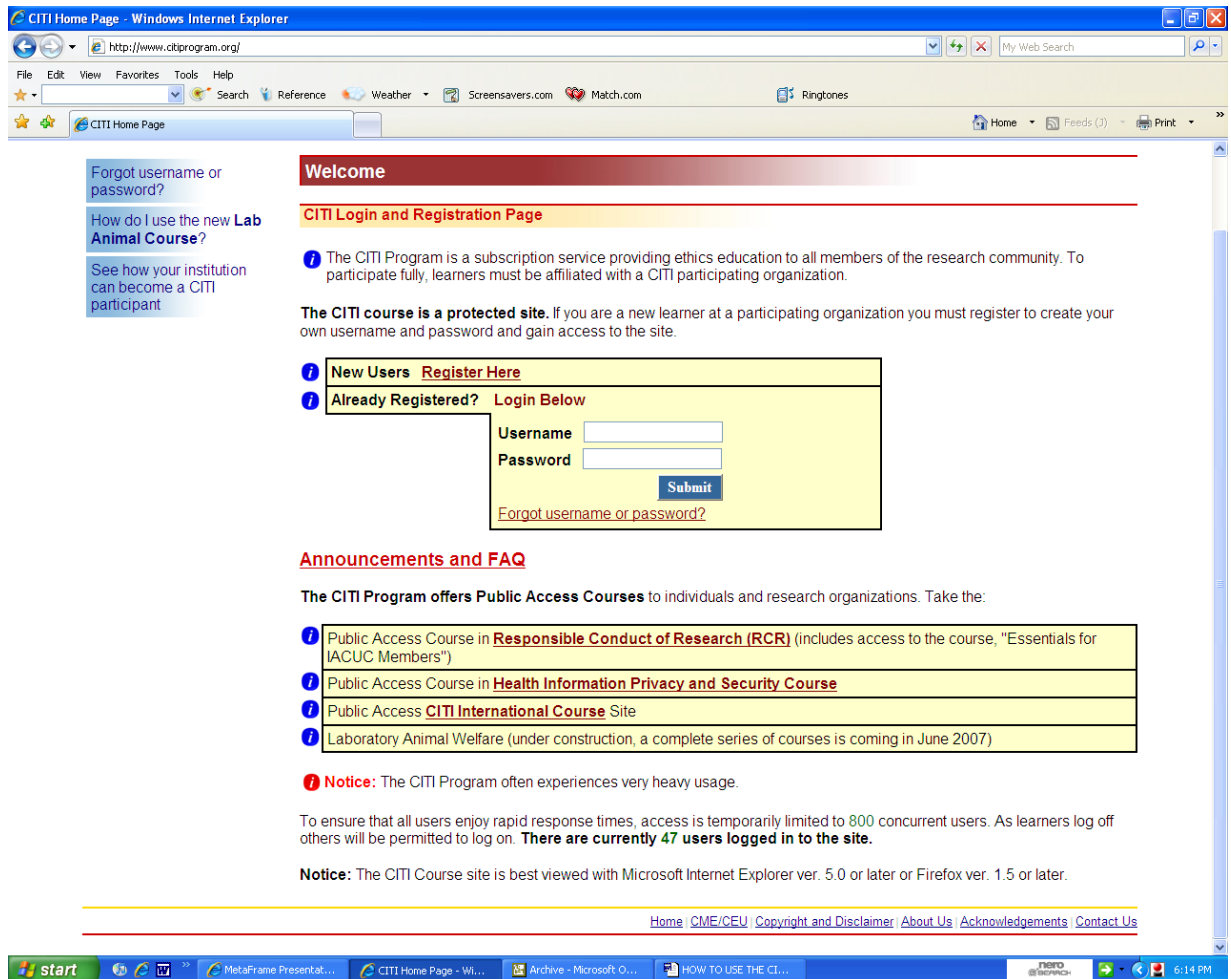
Congratulations you have completed the CITI Course!

All users who have completed the Basic Course are required to take the Refresher Course every 2 years.

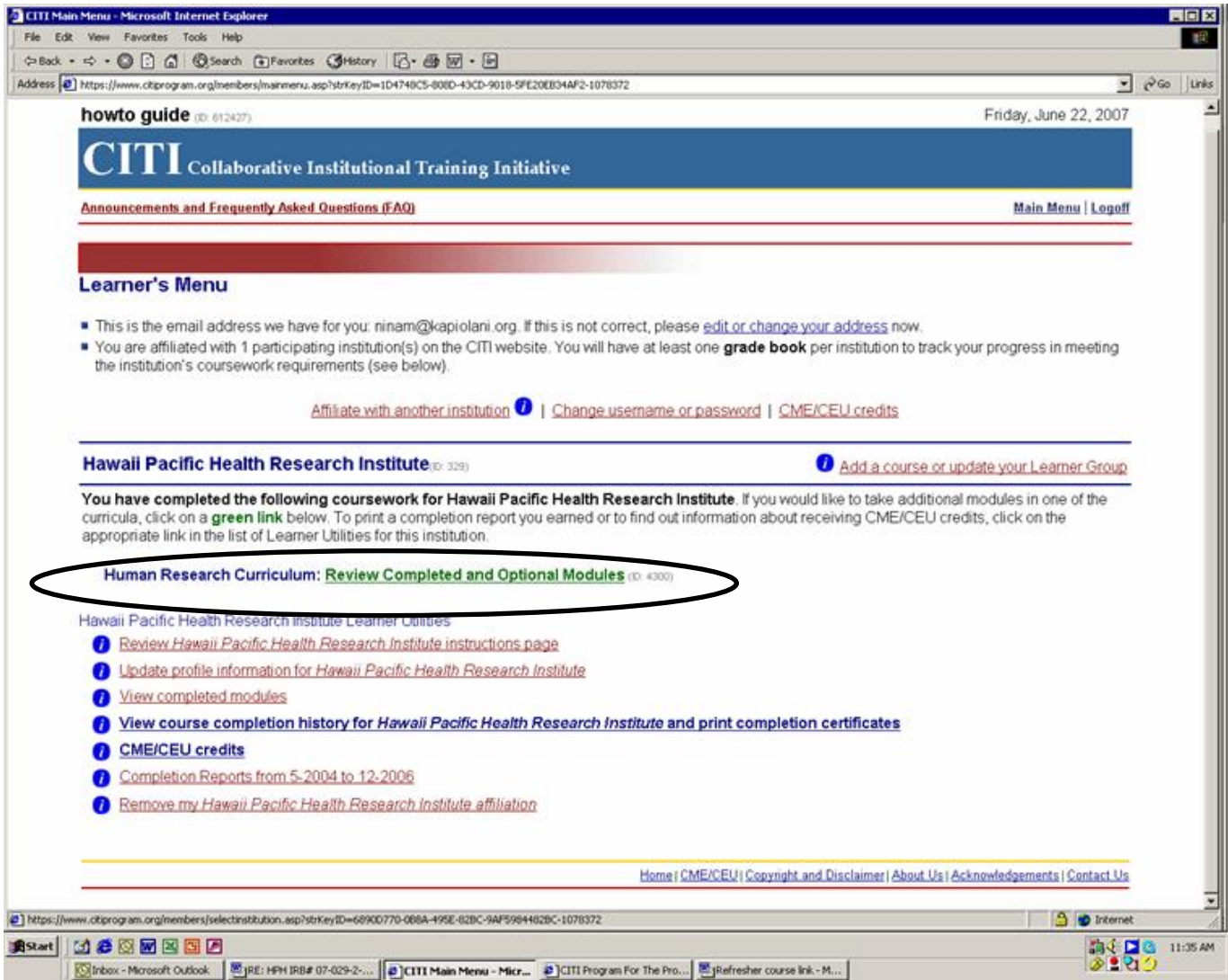
The Refresher Course

If you are required to take the “Refresher Course”, log in to the CITI training site at www.citiprogram.org.

Step 1: Enter your user name and password.



Step 2: Click on the green link, "Review Completed and Optional Modules".

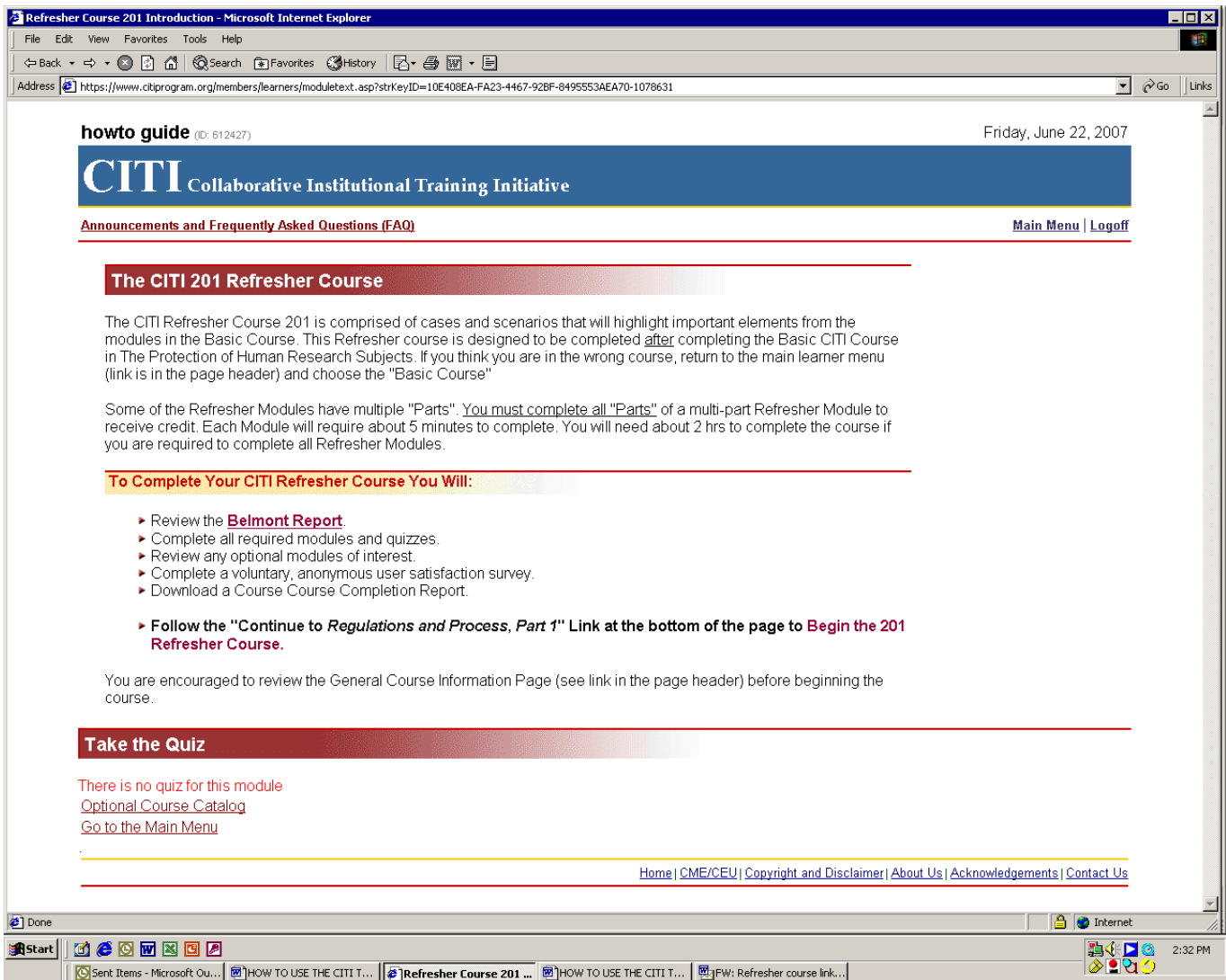


Step 3: Select the link “Refresher Course 201 Introduction.”

The screenshot shows a web browser window titled "Curriculum Catalog - Microsoft Internet Explorer". The address bar contains the URL: <https://www.citprogram.org/members/learners/curriculumcatalog.asp?strKeyID=F4D0CB24-A2CE-471A-8630-2D416684FC9D-1078372>. The page header includes "howto guide (ID: 812427)" and the date "Friday, June 22, 2007". The main heading is "CITI Collaborative Institutional Training Initiative". Below this, there are links for "Announcements and Frequently Asked Questions (FAQ)" and "Main Menu | Logoff". The main content area is titled "Human Research Curriculum Catalog" and contains a table with the following data:

Modules	Date Last Completed	Score
Introduction	06/17/07	100
History and Ethical Principles	06/17/07	60
Basic Institutional Review Board (IRB) Regulations and Review Process	06/18/07	100
Informed Consent	06/18/07	100
Social and Behavioral Research for Biomedical Researchers	06/18/07	75
Records-Based Research	06/18/07	100
Genetic Research in Human Populations	06/18/07	100
Research With Protected Populations - Vulnerable Subjects - An Overview	06/18/07	100
Vulnerable Subjects - Research with Prisoners	06/18/07	100
Vulnerable Subjects - Research Involving Minors	06/18/07	67
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	06/18/07	67
Group Harms - Research With Culturally or Medically Vulnerable Groups	06/18/07	67
FDA-Regulated Research	06/18/07	100
HIPAA and Human Subjects Research	06/18/07	100
Hot Topics	06/18/07	100
Conditions of Interest in Research Involving Human Subjects	06/18/07	100
Refresher Course 201 Introduction	06/22/07	100
History and Ethical Principles	06/22/07	100
Regulations and Process, Part 1	Incomplete	
Regulations and Process, Part 2	Incomplete	

The "Refresher Course 201 Introduction" link is circled in red. The browser's taskbar at the bottom shows several open applications, including "Inbox - Microsoft Outlook", "jRE: H1H 3PB# 07-029-2-...", "Curriculum Catalog - ...", and "jRefresher course link - M...". The system clock shows "11:30 AM".



Step 4: Complete all of the subsequent chapters in the Refresher Course.

Step 5: Print your completion report for your records. An electronic copy will automatically be sent to the Hawaii Pacific Health Research Institute.

Should you need help please contact Christine Nelson at 535-7215 or Christine.Nelson@kapiolani.org