

INSTRUCTIONS FOR CITI GOOD CLINICAL PRACTICE MODULES

Step 1: Open your internet program and go to the CITI website.

<http://www.citiprogram.org>

Step 2: Enter your Username and Password.

If you cannot remember your Username and/or Password click on the “Forgot login information” link and an email will be sent to you. Alternatively, contact Hawai‘i Pacific Health Research Institute at 808-535-7186 for assistance.

The screenshot shows the CITI website interface. At the top is a blue header with the CITI logo and the text "Collaborative Institutional Training Initiative". Below the header is a navigation bar with buttons for Home, Human Subjects Research, Become a Member, HIPS Course, RCR Course, International Course Site, Animal Care and Use, Biosafety, FAQ, and Language. The main content area has a red "Welcome" banner followed by a yellow "CITI Login and Registration Page" banner. A vertical sidebar on the left contains several small images: a planet Saturn, an elderly couple, Stonehenge, a microscope, a person in a lab coat, a butterfly, and a dog. The main text area includes an information icon and a paragraph about the CITI program. Below that is a warning that the site is protected and requires registration. Two links are provided: "New Users Register Here" and "Already Registered? Login Below". The login form consists of "Username" and "Password" input fields and a "Submit" button, all of which are circled in black. Below the form are links for "Forgot login information" and "Contact the CITI Helpdesk". At the bottom, there is a link for "Are You Thinking About Being in a Research Study?" and a notice about user limits and browser requirements.

Welcome

CITI Login and Registration Page

i The CITI Program is a subscription service providing research ethics education to all members of the research community. To participate fully, learners must be affiliated with a CITI participating organization.

The CITI course is a protected site. If you are a new learner at a participating organization you must register to create your own username and password and gain access to the site.

i **New Users** [Register Here](#)

i **Already Registered?** [Login Below](#)

Username

Password

[Forgot login information](#)

[Contact the CITI Helpdesk](#)

Are You Thinking About Being in a Research Study? [Click here](#)

To ensure that all users enjoy rapid response times, access is temporarily limited to 3000 concurrent users. As learners log off others will be permitted to log on. **There are currently 1189 users logged in to the site.**

Notice: The CITI Course site is best viewed with Microsoft Internet Explorer ver. 6.0 or later or Firefox ver. 2.0 or later, and with the characters set to UTF-8.

Step 3: Once you have logged onto the CITI website the following screen will appear.

howto guide (Member ID: 612427)

Main Menu

- This is the email address we have for you: hphri@kapiolani.org. If this is not correct, click [here](#) to edit your email address and other account information including your security question and answer.
- 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).

[Affiliate with another institution](#) ⓘ | [Change login information](#) | [Click here to Apply for CME/CEU Credits](#)

Hawaii Pacific Health Research Institute

ⓘ [View Hawaii Pacific Health Research Institute instructions page](#)

You have enrolled for the following courses:

ⓘ My Courses	Status	Completion Reports	CME/CEU Credits	ⓘ Voluntary Satisfaction Survey
Group 1. BIOMEDICAL, Refresher Course	Incomplete - Re-enter	Not Earned	N/A	Not Available

ⓘ [Add a course or update your learner groups for Hawaii Pacific Health Research Institute](#)

Hawaii Pacific Health Research Institute Learner Utilities

- ⓘ [Optional Modules](#) (completion is completely voluntary and will not count toward a completed course)
- ⓘ [Update my profile information](#) for Hawaii Pacific Health Research Institute
- ⓘ [See a list of all modules that you have completed](#) (goes back to approximately May 2005)
- ⓘ [Click here to see your previously completed coursework for Hawaii Pacific Health Research Institute](#)
- ⓘ [Remove my affiliation](#) from Hawaii Pacific Health Research Institute

Step 4: Click on the link that says “Add a course or update your learner groups for Hawai‘i Pacific Health Research Institute” (circled).

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[Add a course or update your learner groups for Hawaii Pacific Health Research Institute](#)

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- ⓘ [Remove my affiliation from Hawaii Pacific Health Research Institute](#)

Step 5: The following screen will appear. Go to Question 3 (last question) and choose YES.

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Select Curriculum - Hawaii Pacific Health Research Institute

[Review the Hawaii Pacific Health Research Institute Instructions page.](#)

Question1 Human Subject research

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.

I only want to take Good Clinical Practice Course (Please go to Question # 3)

Question2 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.

Question3 Good Clinical Practice Course

Do you need to take the Good Clinical Practice Course (GCP)?

Choose one answer

Yes

No

[Continue](#) [Cancel](#)

Step 6: Good Clinical Practice will now show up under My Courses. Click on the red link “Enter” to begin.

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Main Menu

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Hawaii Pacific Health Research Institute

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You have enrolled for the following courses:

ⓘ My Courses	Status	Completion Reports	CME/CEU Credits	ⓘ Voluntary Satisfaction Survey
Good Clinical Practice (GCP), GCP	Not Started - Enter	Not Earned	N/A	Not Available
Group 1. BIOMEDICAL, Refresher Course	Incomplete - Re-enter	Not Earned	N/A	Not Available

ⓘ [Add a course or update your learner groups for Hawaii Pacific Health Research Institute](#)

Hawaii Pacific Health Research Institute Learner Utilities

- ⓘ [Optional Modules](#) (completion is completely voluntary and will not count toward a completed course)
- ⓘ [Update my profile information for Hawaii Pacific Health Research Institute](#)
- ⓘ [See a list of all modules that you have completed \(goes back to approximately May 2005\)](#)
- ⓘ [Click here to see your previously completed coursework for Hawaii Pacific Health Research Institute](#)

Step 7: Once you have entered the Good Clinical Practice course you will be asked to complete “The Integrity Assurance Statement”. Click on the red link to begin.

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CR# 6037247: Good Clinical Practice (GCP) Gradebook

To pass this course you must complete all required modules with a combined score of 75. Your current score is 0.

Required Modules	Date Complete	Score
Complete The Integrity Assurance Statement before beginning the course.		
GCP Introduction	Incomplete	
Overview of New Drug Development	Incomplete	
International Conference on Harmonisation (ICH): GCP Requirements	Incomplete	
International Conference on Harmonisation - ICH for Investigators	Incomplete	
Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	Incomplete	
Investigator Obligations in FDA-Regulated Clinical Research	Incomplete	
Managing Investigational Agents According to GCP Requirements	Incomplete	
Conducting Clinical Trials of Medical Devices	Incomplete	
Informed Consent-An Ongoing Process	Incomplete	
Detection and Evaluation of Adverse Events	Incomplete	
Reporting Serious Adverse Events	Incomplete	
Audits and Inspections in Clinical Trials	Incomplete	
Monitoring of Clinical Trials by Industry Sponsors	Incomplete	
Completing the CITI GCP Course	Incomplete	

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Step 8: Once you have completed “The Integrity Assurance Statement” the following screen will appear and you will be able to start the Good Clinical Practice modules. Click on the red link “GCP Introduction” to begin.

howto guide (Member ID: 612427)



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CR# 6037247: Good Clinical Practice (GCP) Gradebook

To pass this course you must complete all required modules with a combined score of 75. Your current score is 0.

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

Required Modules	Date Complete	Score
GCP Introduction	Incomplete	
Overview of New Drug Development	Incomplete	
International Conference on Harmonisation (ICH): GCP Requirements	Incomplete	
International Conference on Harmonisation - ICH for Investigators	Incomplete	
Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	Incomplete	
Investigator Obligations in FDA-Regulated Clinical Research	Incomplete	
Managing Investigational Agents According to GCP Requirements	Incomplete	
Conducting Clinical Trials of Medical Devices	Incomplete	
Informed Consent-An Ongoing Process	Incomplete	
Detection and Evaluation of Adverse Events	Incomplete	
Reporting Serious Adverse Events	Incomplete	
Audits and Inspections in Clinical Trials	Incomplete	
Monitoring of Clinical Trials by Industry Sponsors	Incomplete	
Completing the CITI GCP Course	Incomplete	

Step 9: At the end of each module you will be asked to complete a short quiz (unless there is no quiz for a particular module). Once you have completed the quiz you will automatically be taken to the next module.

The Good Clinical Practice course will take between 2-4 hours to complete depending on your familiarity with the material. You will need a combined score of 75 to pass the course. Once you have completed the course you may print your completion certificate for your records. Notification of completion will automatically be sent to Hawai‘i Pacific Health Research Institute.