BRI CITI Training Website Instructions
IRB Biomedical Ethics and GCP

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BACKGROUND

The BRI Research Protections Department (RPD) has limited the requirements for IRB Biomedical Ethics and GCP training to one program, the Collaborative Institutional Training Initiative (CITI), for the following reasons:

- Ensures standardized training;
- 24/7 online accessibility;
- Electronic documentation of completion provided directly to the RPD;
- Semi-annual review and updating of courses and development of new initiatives for the program; and
- Used by thousands of institutions and facilities around the world.

You will need to score 80% or higher on each module to fulfill your requirement. If you score lower than 80%, you can re-take the test as many times as you need with no penalty. When

you have completed all required modules, a certificate of completion will be automatically emailed to you and the RPD.

During the course of completing the modules, if you need assistance, contact the RPD at (206) 342-6917 for guidance. You may also contact the CITI Office at the University of Miami at (888) 529-5929 or by e-mail at support@citiprogram.org.

<u>WHAT DO I NEED TO COMPLETE?</u>

1. All VM/BRI researchers considered "key personnel" are required to complete the "Basic CITI Course in the Protection of Human Research Subjects" (Basic Course) and Good Clinical Practice (GCP) modules. Certain researchers may qualify for an exemption from GCP training if they do not work with VM/BRI patients or subjects directly, their records or identifiable information, or identifiable samples (see "DO I QUALIFY FOR AN EXCEPTION?").
2. VM/BRI researchers having completed the "Basic Course", must complete the "Refresher Course in the Protection of Human Research Subjects" (Refresher Course) and GCP modules every 3 years.
3. Researchers not directly affiliated with VM/BRI (e.g. UW, SCH, FHCRC) may qualify for an exception if they have completed training at their own institution (see "DO I QUALIFY FOR AN EXCEPTION?").
4. Ensure your institutional email address is set to either your VM or BRI email account. This can be done by clicking on "Profile" under your name in the top right of the main menu. Click on "Edit Profile."

WHO IS CONSIDERED KEY PERSONNEL?

Persons responsible for one or more of the following:

- Day-to-day protocol decision-making related to the study conduct;
- Participant recruitment, selection and eligibility;
- Clarification of the complexities of the protocol to the participant and others;
- Collecting participant information and entering data using procedures to maintain privacy and confidentiality;
- Ensuring that the rights and welfare of participants are monitored throughout the study.

HOW DO I REGISTER?

1. BRI personnel: Go to citi.benaroyaresearch.org to connect to CITI via your BRI account.
2. VM or external personnel: Go to www.citiprogram.org
3. Click "Register" at the top of the page.

4. Select your organization affiliation by searching for "Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI) (SSO)", agree to the terms, affirm you are an affiliate, and then click the "Continue to SSO Login/Instructions" button.

5. You will be prompted to enter your username and password for your VM or BRI email address. Once information is entered and verified, registration is complete.

ADDING COURSES

To add training modules to your account, follow these steps:

1. Go to www.citiprogram.org (or citi.benaroyaresearch.org to connect to CITI via your BRI account, if applicable).

    a. Click "Log In" on the main page.

    b. Enter your username and password. If you don't have these, see section WHAT IF I LOST MY USERNAME AND PASSWORD?

2. Once signed in, you will be taken to the "Main Menu."

3. Click the link "Add a Course."

Learner Tools for Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)

- Add a Course
- Remove a Course
- View Previously Completed Coursework
- Update Institution Profile
- View Instructions Page
- Remove Affiliation

4. You will be prompted with these options to determine which modules you need to complete:

Please choose all courses you need to take:

This question is required. Choose all that apply.

☐ **IRB – Institutional Review Board - Human Subjects Research Course**
- Required for IRB Members, Institutional Officials (IO), Principal Investigators (PI), Coordinators/Research Assistants, or other staff members conducting research on human subjects.
- Select this option if you **only need to complete GCP training**.

☐ **IACUC – Institutional Animal Care and Use Committee - Animal Research Course**
- Required for IACUC Members, Institutional Officials, PIs and Lab Personnel conducting research on animal subjects.

☐ **IBC – Institutional Biosafety Committee Course**
For other lab personnel and staff members determined by the PI to be key personnel on a research protocol with

ⓘ.

- Required for IBC Members, Institutional Officials, PIs, Lab Personnel, or other staff fitting the description above.

☐ Institutional/Signatory Official Courses

☐ IRB Chair

☐ **COI - Research Conflict of Interest**
Required if you must meet at least one of the criteria below:

- Member of Research Oversight Committee
- Investigator/Research Personnel (principal, co- or sub-investigator, or any other person at Virginia Mason who is responsible for, or otherwise involved in, the design, conduct, or reporting of research.)
- Executive leadership, Senior Manager, Compliance Offer.
- Board Member with research oversight responsibilities

5. Please select the group(s) related to your research activities to view available courses and click the "Next" button. (Note: Only select the "Institutional/Signatory Official Courses" or "IRB Chair" options if you hold those titles at this institution.)

6. IRB Human Subjects Research Page:
   a. Select the group appropriate to your research activities:
      i. Group 1 - Biomedical Research Personnel - This course is suitable for Students, Investigators and staff conducting BIOMEDICAL RESEARCH with human subjects.

The VA module must be completed if you plan to work with subjects at a VA facility.

    ii. Group 2 - Social & Behavioral Research Personnel - This course is suitable for Students, Investigators and staff conducting Social & Behavioral Research with human subjects.

    iii. Group 3 - Data or Specimens Only Research Personnel (Take only if you will NEVER interact with a human subject or view their PHI.)

    iv. Group 4 - BRI IRB Members. (Only if you are a member of the BRI IRB)

  b. If you *only* need to complete the GCP course, select the last option

  c. Select a basic course if you have never taken CITI Ethics training at BRI. You must first complete an approved basic course to receive credit for completing a refresher course.

Please choose <u>one</u> of these following courses:

This question is required. Choose one answer.

○ **Group 1: Human Subjects Protection/Good Clinical Practice** [Select if you will be involved in research with Patients or Subjects directly, their records, and/or identifiable information or samples [Biomedical Research].

○ **Group 2: Social & Behavior Research/Good Clinical Practice** (Select if you have never taken this course at BRI and you will ONLY be involved in Social and Behavioral Research with Human Subjects, their records and/or identifiable information.)

○ **Group 3: Anonymous Data/Specimens Only Research Ethics** (Select if you have never taken this course at BRI and you will be involved in research with Data or Specimens **ONLY** and will never have access to any identifiable information [i.e. Protected Health Information (PHI)].)

○ **Group 4: IRB Member Human Subjects Protection/Good Clinical Practice** (Select if you have never taken this course at BRI and you are an IRB Member [Should also be taken if you are a researcher **AND** an IRB member].)

○ **I only need to complete the GCP training: Basic Course** (Select if you have never taken this course at BRI).

7. Once registered, you will be taken to the "Main Menu." You will see "Courses Ready to Begin" for each course you still need to take.

Courses Ready to Begin

Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)

CITI Good Clinical Practice

Stage 1 - GCP

0 / 14 modules completed

Start Now

Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)

Research Conflict of Interest

Stage 1

0 / 3 modules completed

Start Now

Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)

Working with Mice in Research

Stage 1 - Basic Course

0 / 6 modules completed

Start Now

8. To begin, click on "Start Now". You will be directed to the "Assurance Statement".

9. You are required to agree to the "Assurance Statement" before you can begin the course.

Assurance Statement

CITI Good Clinical Practice - GCP Refresher

CITI Program's Terms of Service and Privacy and Cookie Policy include the following provisions for learners. Please read them carefully.

Account Security: I will keep my username and password secure, and I will not share them or allow anyone else to access my account. I will contact CITI Program Support if I believe my account has been compromised.

Work Integrity: I will complete all required quizzes and any other assessments using only my own work. I will not engage in any activities that would dishonestly improve my results, or improve or hurt the results of other learners.

Quiz Sharing: I will not share CITI Program quiz questions or answers on any website, via email, photocopying, or by any other means.

Recordkeeping: I understand that CITI Program keeps account activity logs, including computer IP address, time spent in each content area, number of quiz attempts, and quiz scores. Indications of inappropriate use will be investigated, and may be reported to organizations with which I am affiliated.

☐ I AGREE to the above, the Terms of Service, and the Privacy and Cookie Policy, in order to access CITI Program materials.

Cancel   **Submit**

10. Follow the instructions to complete each module. Tests are located at the bottom of each module.

- U.S. Food and Drug Administration (FDA). 2015. "Home." Accessed February 16.
- U.S. Food and Drug Administration (FDA). 2018. "E6(R2) Good Clinical Practice: Integrated Addendum to E6(R1); International Council for Harmonisation; Guidance for Industry." *Federal Register* 41(83):8882-3.
- U.S. Government Publishing Office (GPO). 2015. "GPO's Federal Digital System: Advanced Search." Accessed February 16.

Original Release: March 2015
Last Updated: March 2018

i This module has a quiz.

Return to Gradebook   **Take the Quiz**

11. You can retake the tests as many times as needed to obtain a satisfactory score.

Return to Gradebook   **View the next required Module**

- Review Module / Retake Quiz *i*
- Leave feedback for this Module
- View Courses

HOW DO I COMPLETE THE REFRESHER COURSE?

Recertification for CITI training must be completed every 3 years for IRB. If you received notification that your training has expired, and you are listed as key personnel on any VM/BRI research studies, you will need to take the CITI "refresher course" and "GCP" at this time:

1. Go to www.citiprogram.org (or citi.benaroyaresearch.org to connect to CITI via your BRI account, if applicable).
    a. Click "Log In" on the main page.

    b. Enter your username and password. If you don't have these, see section WHAT IF I LOST MY USERNAME AND PASSWORD?

2. Once signed in, you will be taken to the "Main Menu." You will see up to three categories of courses: "Active Courses", "Courses Ready to Begin", and "Completed Courses".

3. To begin, click "Start Now" or "Continue Course". You will be directed to the "Assurance Statement".

4. You are required to agree to the "Assurance Statement" before you can begin the course.

Assurance Statement
CITI Good Clinical Practice - GCP Refresher

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Work Integrity: I will complete all required quizzes and any other assessments using only my own work. I will not engage in any activities that would dishonestly improve my results, or improve or hurt the results of other learners.

Quiz Sharing: I will not share CITI Program quiz questions or answers on any website, via email, photocopying, or by any other means.

Recordkeeping: I understand that CITI Program keeps account activity logs, including computer IP address, time spent in each content area, number of quiz attempts, and quiz scores. Indications of inappropriate use will be investigated, and may be reported to organizations with which I am affiliated.

☐ I AGREE to the above, the Terms of Service, and the Privacy and Cookie Policy, in order to access CITI Program materials.

[Cancel] [Submit]

5. Follow the instructions to complete each module. Tests are located at the bottom of each module.

- U.S. Food and Drug Administration (FDA). 2015. "Home." Accessed February 16.
- U.S. Food and Drug Administration (FDA). 2018. "E6(R2) Good Clinical Practice: Integrated Addendum to E6(R1); International Council for Harmonisation; Guidance for Industry." *Federal Register* 41(83):8882-3.
- U.S. Government Publishing Office (GPO). 2015. "GPO's Federal Digital System: Advanced Search." Accessed February 16.

Original Release: March 2015
Last Updated: March 2018

> ⓘ This module has a quiz.
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> ---
>
> [Return to Gradebook]   [**Take the Quiz**]

6. You can retake the tests as many times as needed to obtain a satisfactory score.

> ---
>
> [**Return to Gradebook**]   [**View the next required Module**]
>
> ---
>
> - Review Module / Retake Quiz ⓘ
> - Leave feedback for this Module
> - View Courses

DO I QUALIFY FOR AN EXCEPTION?

An exemption to the GCP training requirement may be available for "key personnel" that do not work with VM/BRI patients or subjects directly, their records or identifiable information, or identifiable samples. Please email CRP@benaroyaresearch.org with your request for exemption. Be sure to include the IRB number of the study you wish to be exempted from and clearly state will not work with VM/BRI patients or subjects directly, their records or identifiable information, or identifiable samples.

An exception is available for "key personnel" completing ethics training at another institution (i.e. outside VM/BRI). The institution must have a current Federal-wide Assurance (FWA) and documentation of training for each person must be provided to the BRI RPD office. Documentation via hardcopy or e-mail is acceptable, or you may provide a web-link to your institution's ethics training listing.

ADDING CONFLICT OF INTEREST TRAINING?

All researchers meeting at least one of the criteria below are required to complete/add the "COI – Research Conflict of Interest" training:

- Member of Research Oversight Committee (i.e. IRB, IBC, IACUC).
- Investigator/Research Personnel on any current of future study (e.g. principal, co- or sub- investigator, or any other person at BRI/VM who is responsible for, or otherwise involved in, the design, conduct, or reporting of research.)
- Executive leadership, Senior Manager, Compliance Officer.
- Board Members with research oversight responsibilities.

To add training modules to your account, follow these steps:

1. Go to www.citiprogram.org (or citi.benaroyaresearch.org to connect to CITI via your BRI account, if applicable).

    a. Click "Log In" on the main page.

    b. Enter your username and password. If you don't have these, see section WHAT IF I LOST MY USERNAME AND PASSWORD?

CITI PROGRAM

LOG IN   LOG IN THROUGH MY INSTITUTION   REGISTER

| fakename0 | Forgot? |
| .... | Forgot? |

Log In

Need Help? Support Center

2. Once signed in, you will be taken to the "Main Menu."

3. Click the link "Add a Course."

Learner Tools for Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)

- Add a Course
- Remove a Course
- View Previously Completed Coursework
- Update Institution Profile
- View Instructions Page
- Remove Affiliation

4. You will be prompted with these options to determine which modules you need to complete:

Please choose all courses you need to take:

This question is required. Choose all that apply.

☐ **IRB – Institutional Review Board - Human Subjects Research Course**
- Required for IRB Members, Institutional Officials (IO), Principal Investigators (PI), Coordinators/Research Assistants, or other staff members conducting research on human subjects.
- Select this option if you **only need to complete GCP training**.

☐ **IACUC – Institutional Animal Care and Use Committee - Animal Research Course**
- Required for IACUC Members, Institutional Officials, PIs and Lab Personnel conducting research on animal subjects.

☐ **IBC – Institutional Biosafety Committee Course**
For other lab personnel and staff members determined by the PI to be key personnel on a research protocol with

ⓘ.

- Required for IBC Members, Institutional Officials, PIs, Lab Personnel, or other staff fitting the description above.

☐ Institutional/Signatory Official Courses

☐ IRB Chair

☐ **COI - Research Conflict of Interest**
Required if you must meet at least one of the criteria below:

- Member of Research Oversight Committee
- Investigator/Research Personnel (principal, co- or sub-investigator, or any other person at Virginia Mason who is responsible for, or otherwise involved in, the design, conduct, or reporting of research.)
- Executive leadership, Senior Manager, Compliance Offer.
- Board Member with research oversight responsibilities

3. Please select the box next to "COI – Research Conflict of Interest" and click the "Next" button.

4. Once registered, you will be taken to the "Main Menu." Under "Courses Ready to Begin" you will see "COI – Financial Conflicts of Interest Course".

5. To begin, click "Start Now". You will be directed to the "Assurance Statement".

6. You are required to agree to the "Assurance Statement" before you can begin the course.

Assurance Statement
CITI Good Clinical Practice - GCP Refresher

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Work Integrity: I will complete all required quizzes and any other assessments using only my own work. I will not engage in any activities that would dishonestly improve my results, or improve or hurt the results of other learners.

Quiz Sharing: I will not share CITI Program quiz questions or answers on any website, via email, photocopying, or by any other means.

Recordkeeping: I understand that CITI Program keeps account activity logs, including computer IP address, time spent in each content area, number of quiz attempts, and quiz scores. Indications of inappropriate use will be investigated, and may be reported to organizations with which I am affiliated.
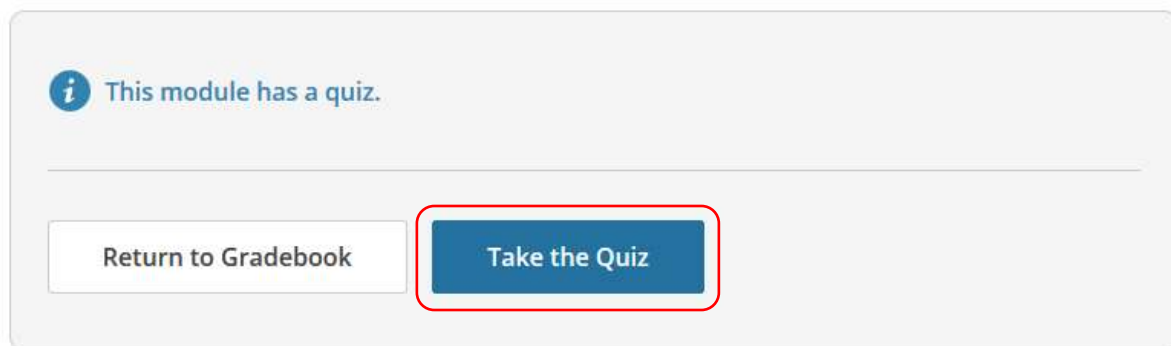
☐ I AGREE to the above, the **Terms of Service**, and the **Privacy and Cookie Policy**, in order to access CITI Program materials.

Cancel   **Submit**

7. Follow the instructions to complete each module. Tests are located at the bottom of each module.

- U.S. Food and Drug Administration (FDA). 2015. "Home." Accessed February 16.
- U.S. Food and Drug Administration (FDA). 2018. "E6(R2) Good Clinical Practice: Integrated Addendum to E6(R1); International Council for Harmonisation; Guidance for Industry." *Federal Register* 41(83):8882-3.
- U.S. Government Publishing Office (GPO). 2015. "GPO's Federal Digital System: Advanced Search." Accessed February 16.

Original Release: March 2015
Last Updated: March 2018

ℹ This module has a quiz.

Return to Gradebook   **Take the Quiz**

8. You can retake the tests as many times as needed to obtain a satisfactory score.

WHAT IF I LOST MY USERNAME AND PASSWORD?

This should not be an issue for BRI personnel, as the Single Sign-On feature should automatically connect you to CITI through your BRI credentials. If you are VM or other outside personnel, and do not remember your username and/or password, follow these steps:

1. Go to www.citiprogram.org and click "Log In."
2. Click on "Forgot?" next to the username or password.

CITI PROGRAM

LOG IN   LOG IN THROUGH MY INSTITUTION   REGISTER

| Username | Forgot? |
| Password | Forgot? |

Log In

New to the CITI Program? Read the getting started guide or watch the getting started video.

Need Help? Support Center

3. If you need your username, follow the directions in the section "Retrieve Your CITI Username" to request your username be emailed to you.

Retrieve your CITI Username

If you have forgotten your username, enter an email address that you used for registration of that account. Your username will be sent to this email address.

Email Address

Send My Username

Need to reset your CITI password instead?

4. If you have forgotten your password, follow the directions in the section "Reset Your CITI Password" to set up a new password.

Need to retrieve your CITI username instead?

NOTE: Your username and email address used to complete the Basic CITI ethics course is located on the top of your original course completion certificate. Contact the RPD office at: IRB@benaroyaresearch.org if you need assistance.

HOW DO I AFFILIATE WITH VM/BRI?

If you are new to Virginia Mason or Benaroya Research Institute, and you already have a CITI account through your previous institution:

1. Go to www.citiprogram.org and click "Log In" on the main page.

2. Enter your username and password. If you don't have these, see section WHAT IF I LOST MY USERNAME AND PASSWORD?

CITI PROGRAM

LOG IN   LOG IN THROUGH MY INSTITUTION   REGISTER

fakename0	Forgot?
··········	Forgot?

Log In

Need Help? Support Center

3. Once signed in, you will be taken to the "Main Menu."

4. Select the "Add Affiliation" option on "Would you like to affiliate with another institution?"

Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to **add an affiliation**. If you are no longer associated with a listed institution, you may want to **remove an affiliation**.

DEMO   **View Courses**

Virginia Mason (VM)/Benaroya Research Institute at   **View Courses**
Virginia Mason (BRI)

Would you like to affiliate with another Institution?   **Add Affiliation**

Would you like to remove an existing affiliation?   **Remove Affiliation**

5. Select your organization affiliation by searching for "Virginia Mason (VM)/Benaroya Research Institute at Virginia Mason (BRI)" and then agree to the Terms of Service.

6. You will be prompted to answer basic information about yourself. Once this is complete, you will be affiliated with VM/BRI.

7. Ensure your institutional email address is set to either your VM or BRI email account. This can be done by clicking on "Profile" under your name in the top right of the main menu. Click on "Edit Profile."

HOW DO I OBTAIN CME CREDITS?

Six (6) Category I CME credits are available for Physicians, Physician Assistants, Nurse Practitioners and Psychologists who complete the "Basic Course." The credits are available through the University of Miami Office Continuing Medical Education for a handling fee of $60 - $70.

Two (2) Category I CME credits are available for Physicians, Physician's Assistants, Nurse Practitioners and Psychologists who complete the "Refresher Course" for a handling fee of $40 - $50.

Please call (888) 529-5929 for information specific to CME credits or see the CITI web-site link https://support.citiprogram.org/customer/portal/articles/1719368 for additional instructions.

For additional questions about CITI: support.citiprogram.org