MedStar Health

Investigator/Research Staff for Human Subjects Training

Frequently Asked Questions

Who needs to complete research training?

Any individual engaged in human subjects research is required to have training.

A person is engaged in research, regardless of their designation as a principal investigator, sub-investigator, collaborator, fellow/resident, research coordinator, laboratory personnel or other support staff, if involved in performing, assisting with, or supervising: (1) study procedures performed for research purposes; (2) recruitment/enrollment of potential study participants; (3) the research informed consent process; (3) collecting, interpreting, or contributing to the analysis of research data; (4) communicating the results of research through scientific presentation or publication of abstracts and/or manuscripts; or (5) any other important study-related decisions.

What training needs to be completed?

Courses required for all investigators/research staff depending on study type:

Biomedical	Social & Behavioral
Investigators/Research Staff (ID: 4192) OR Clinical Research Coordinators/Clinical Research Personnel (CRC/CRP)	Investigators/Research Staff – SBE (ID: 128962) OR Clinical Research Coordinators/Clinical Research Personnel (CRC/CRP)

Courses required for NIH funded studies **OR** NIH funded fellows and trainees:

Biomedical	Social & Behavioral
GCP for Clinical Investigations of Devices (ID: 128958) OR GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) (ID: 128957) OR Good Clinical Practice Course	Good Clinical Practice – Social Behavioral (ID: 132575) OR Good Clinical Practice Course

Courses required for PHS-funded research:
- Conflicts of Interest (ID: 96449)

How long is my training good for?

Training expiration dates have been set for three (3) years. However, your sponsor may require training more frequently.
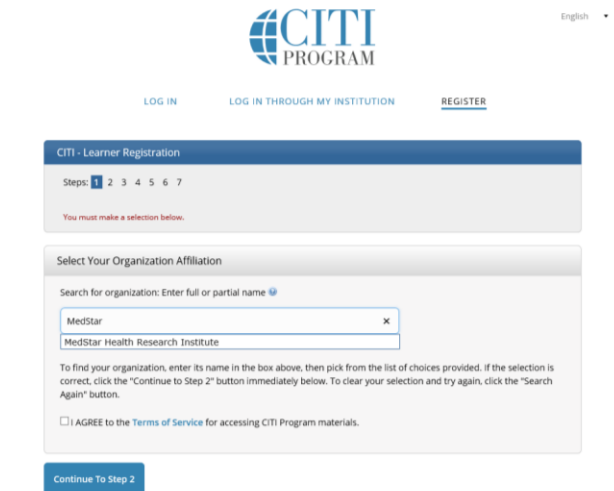
How do I complete the training?

Training is done through the Collaborative Institutional Training Initiative (CITI)
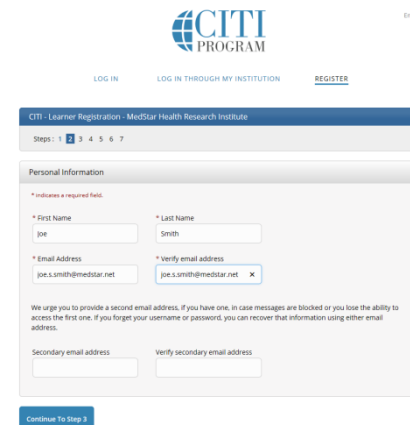
- Go directly to CITI: https://www.citiprogram.org/
- Register or Login
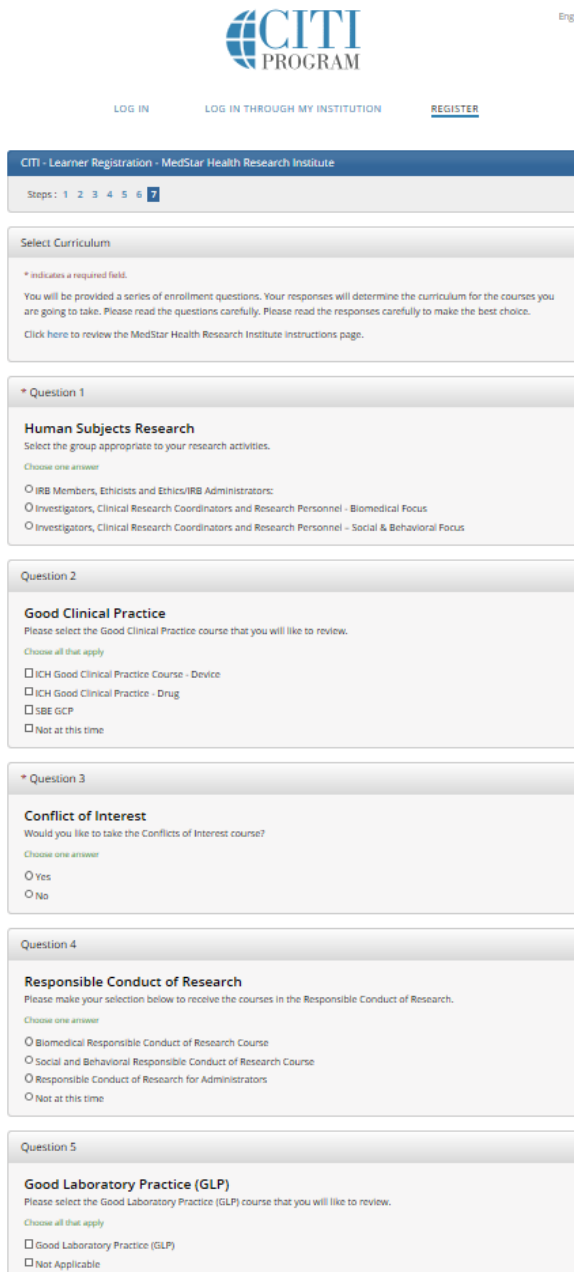 - o To register, hit the "Register" button on upper right
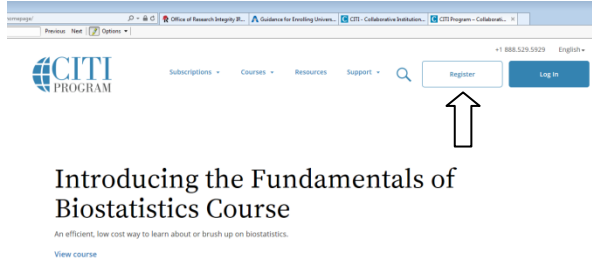
  - o On the registration screen, select "MedStar Health Research Institute" under the search for organization.

  - o Enter Personal Information and Create username and password

- o Save username and password for future reference
- o Continue through steps entering in information requested
- o Step 7: Select Curriculum. Review the available courses and select your required courses. Refer to "What training needs to be completed?" question above to make the required selections.

- Complete registration

How long does training take?
Estimates are 3-6 hours to complete the modules, depending on your experience and number of modules required.

Do I have to do all the training in one sitting?
No. You may begin modules, save and return at a later time

How does ORI know that I've done my training?
MHRI – ORI has access to CITI to verify your completed training. Completed training is verified prior to IRB review for both initial and continuing review submissions. Failure to complete all required training can lead to delays IRB review.

### What if I did training for another institution? Would MHRI IRB accept that training?
Yes. To allow for verification of your training by MHRI ORI, you will either need to affiliate to MHRI or provide certificates of completion of equivalent or comparable training. If you affiliate your profile with MHRI, your completion certificates can be seen by MHRI ORI. If training requirements differ between your original institution and MHRI and are not deemed to be equivalent or comparable, you may be asked to take additional modules.

To affiliate your account with MHRI:

- Log into the CITI system and affiliate with MedStar Health Research Institute (MHRI) by selection on the Main Menu "Affiliate with Another Institution
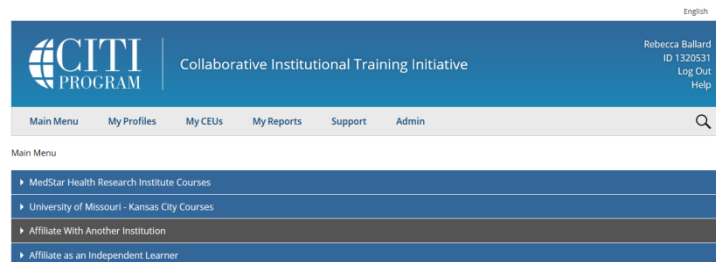
- Choose "Affiliate with Another Institution"
- Select the Organization to become Affiliated by searching for "MedStar Health Research Institute"
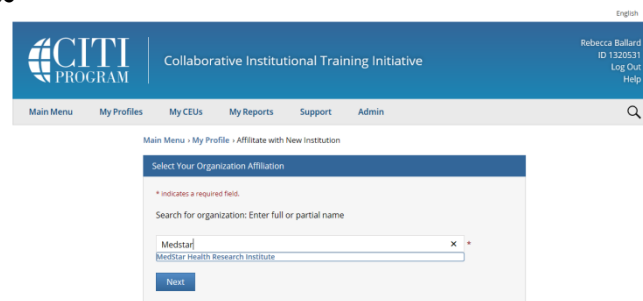
- You may be asked to complete a few additional sections that are relevant to MHRI
- Best practice is to PRINT/SAVE your CITI training certificate for your records.

What happened to PEER numbers?

Finding and providing your PEER number in IRB forms **will no longer be required**. Just leave blank any question asking for your PEER number.

Click here to learn more about this change.

How can I confirm my CITI training status?

- Login into CITI and review your courses under MedStar Health Research Institute Courses.
- Click "View Previously Completed Coursework" to see your training history.

My Learner Tools for MedStar Health Research Institute
- Add a Course
- Remove a Course
- View Previously Completed Coursework
- Update Institution Profile
- View Instructions page
- Remove Affiliation

Review the status column by each course. Courses recently taken will indicate the date. Outstanding courses will indicate they are "Due Now". Courses remaining will indicate "Not Started"

Curricula Information

Course	Stage	CR #	Status	View
GCP – Social and Behavioral Research Best Practices for Clinical Research	Basic Course	24676875	Passed - 09/20/17	Modules Completed
GCP for Clinical Investigations of Devices	GCP	24676873	Not Started	Gradebook
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)	Basic Course	24676872	Not Started	Gradebook
Investigators/Research Staff - SBE	Basic Course	24676874	Passed - 09/20/17	Modules Completed
Social and Behavioral Responsible Conduct of Research	RCR	24679734	Not Started	Gradebook

If you have issues in verifying training, then contact the Office of Research Integrity at MHRI-ORIHelpDesk@MedStar.net or call **301-560-2912**.