MHRI IRB Required Compliance training for Investigator/Research Staff

Applicability of Training Requirements

These requirements apply to all individuals conducting research on behalf of MedStar health or any MedStar health affiliated institution / organization that falls under the jurisdiction of the MedStar Health Research Institute (MHRI) Human Research Protections Program (HRPP).

These requirements apply without regard to the individuals role on the research team (i.e. principal investigator, sub- investigator, collaborator, fellow/resident, research coordinator, laboratory personnel or other support staff, if involved in performing, assisting with, or supervising research activity including (but not limited to): (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 are dependent on the study type. Additionally, Clinical Research Coordinators and Regulatory Coordinators have requirements for MedStar-specific training outside of CITI that is defined in other institutional SOP:

Biomedical	Social / Behavioral/ Educational
All study team members: Biomedical Comprehensive Human Subjects Protections	All study team members: Social – Behavioral – Educational Human Subjects Protection (SBE) Comprehensive

The following GCP Courses meet NIH and FDA standards and are required for:

NIH funded or supported studies **and** studies with NIH funded fellows and trainees

All FDA regulated research

Biomedical	Social & Behavioral
All Study team members: GCP Drugs and Devices FDA	All Study team members: GCO – Social and Behavioral Research Best Practices for Research

Courses required for Federal Funded research:
- Conflicts of Interest (ID: 96449)

How long is my training good for?

MHRI required training is valid for three (3) years. Investigators should verify if the sponsor or funding source requires recertification of training at a more frequent interval.
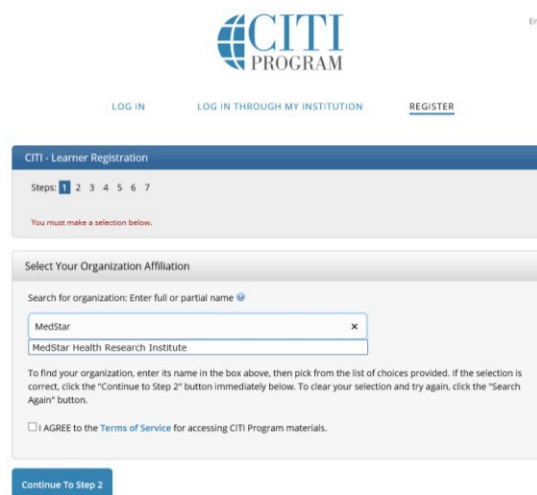
How do I complete the training?

Training is done through the Collaborative Institutional Training Initiative (CITI)

- Go directly to CITI: https://www.citiprogram.org/
- If you do not already have an account complete registration. If you have an active account login.
  - o To register, click the "Register" button on upper right

  - o On the registration screen, select "MedStar Health Research Institute" under the search for organization.

  - o Then select the check boxes to move forward to the next step.

  - 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

To affiliate an existing account with MedStar:

- Log into the CITI system and affiliate with MedStar Health Research Institute (MHRI) by selection on the Main Menu "Affiliate with Another Institution
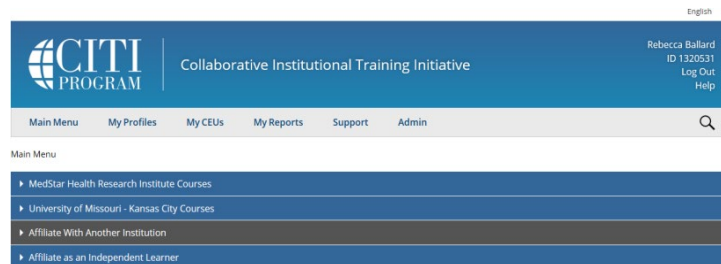
- Choose "Affiliate with Another Institution"
- Select the Organization to become Affiliated by searching for "MedStar Health Research Institute"
- Select the checkboxes to move on to the next step.
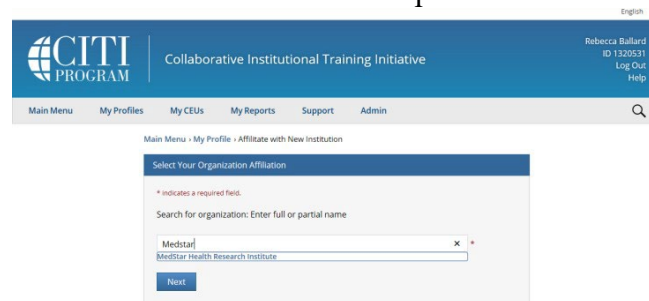
- You may be asked to complete a few additional sections that are relevant to MHRI

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.

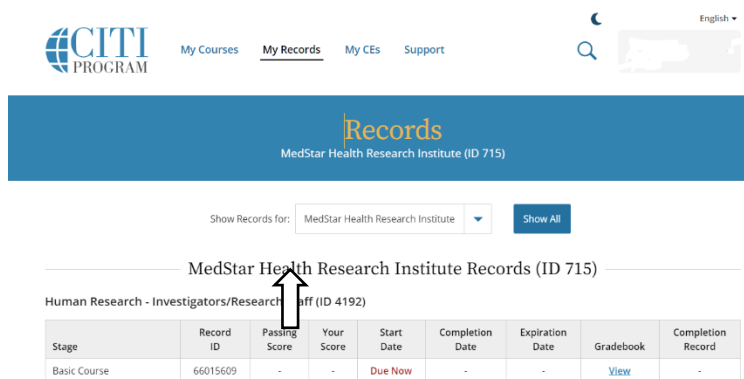### How does ORI know that I've done my training?

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?

No. Because CITI training may be customized not all institutions have equivalent training. Each MedStar affiliate must complete the MedStar specific CITI training. However, if you have completed CITI training for another institution you will receive credit for any modules that are consistent with MedStar requirements. In this way you may receive partial (or full) credit from prior courses towards MedStar requirements. If that is the case you will be required to complete only the additional modules that are required by MedStar.

How can I confirm my CITI training status?

- Login into CITI and Click "My Records" to review your courses.
- Select "MedStar Health Research Institute" in the drop-down menu for "Show records for:"

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"

MedStar Health

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**.

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