

Initiating a New Study Guidance for Fairview Researchers

When a Fairview researcher is starting a new study, Fairview Research Administration (FRA) is responsible for providing guidance to ensure compliance with the following requirements.

Definition of a Fairview Researcher

Fairview Researchers include all medical staff appointees, students, physicians privileged to practice at Fairview, and employees of Fairview who participate in research involving human subjects at any Fairview facility. *This definition specifically excludes University of Minnesota faculty and students.*

Human Subjects Protection Training

Fairview Researchers must complete human subjects protection training every 3 years. This training is available through the CITI site (www.citiprogram.org). The training you complete is dependent on what research activities you will do.

Conflict of Interest Training

Fairview Researchers must complete Conflict of Interest (COI) training every 3 years. This training is also available through the CITI site. The training is the same for all researchers.

Conflict of Interest Disclosure

Fairview Researchers must complete COI disclosures at least annually. You should update your disclosure if your institutional responsibilities or financial or business interests change. More information about the COI process and the disclosure form are available on FRA's [COI website](#).

IRB Application Completeness

FRA is happy to assist with development of your IRB application! To start the process, send FRA a synopsis of your study. We will provide direction on which forms to complete.

Please do not submit your application to the IRB. Send your application to FRA. We will review it for completeness and offer feedback if requested. FRA will submit the application to the IRB on your behalf.

FRA needs to be included as a correspondent on every IRB application with a Fairview Researcher listed. Here is our information:

Name (Last name, First name MI): Fairview Research	Highest Earned Degree:
Mailing Address: 2344 Energy Park Drive Saint Paul, MN 55108	Phone Number: 612 672 7690
	Fax: 612 672 7691
U of M Employee/Student ID:	Email: research@fairview.org
Occupational Position: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/> Fairview Researcher <input type="checkbox"/> Gillette Researcher <input checked="" type="checkbox"/> Other: correspondent	
Human Subjects Training <input checked="" type="checkbox"/> CITI , <input type="checkbox"/> Investigator 101, <input type="checkbox"/> NIH training (EXCEPT for 5/8/06 to 2/29/08), <input type="checkbox"/> Other - Indicate training received, when and from which institution:	HIPAA Training: <input checked="" type="checkbox"/> HIPAA

Questions? Contact FRA at 612-672-7690 or research@fairview.org.

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Appendix B: CITI Training

1. Go to www.citiprogram.org
2. If you are a new user, create an account by clicking 'Register'.
Select Fairview Health Services from the list of Participating Institutions. This is critically important!
Follow the prompts to complete registration.

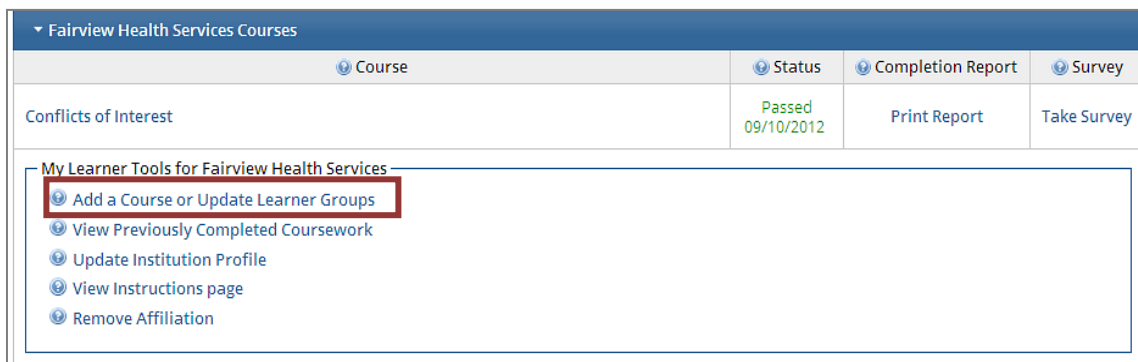
If you are already registered, sign in. Follow the 'Forgot username or password' prompts if needed. FRA can look up your username if you are affiliated with Fairview Health Services in CITI.



3. Click on 'Fairview Health Services Courses' to expand the menu.
If Fairview Health Services is not an option, select 'Click here to affiliate with another institution' to affiliate with Fairview Health Services.



4. Click 'Add a Course or Update Learner Groups'



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5. If you already completed human subjects protections training, select 'N/A' for Question 1.
If you never completed human subjects protections training, select the group that mostly closely matches your research role. If you aren't sure which group to choose, ask FRA.

Question 1

Select the group appropriate to your research activities.

Choose one answer

- Group 1: Biomedical Research Investigators and Key Personnel
- Group 2: Social & Behavioral Research Investigators and Key Personnel
- Group 3: Research with Records and/or Specimens Only.
- Group 4: Staff/Floor Nursing personnel NOT involved with a research protocol requiring Informed Consent training.
- IRB Reference Resource: All CITI modules are available for ongoing use and reference when you join this Learner Group. However, if you are required to complete the CITI modules as a prerequisite for conducting human subjects research, you must enroll in Group 1, 2 or 3 above and complete the required course content to receive "credit" for the course. You may change your Learner Group status later to "IRB Reference Resource" for ongoing access and resource use of all CITI modules.

N/A

6. Question 2 is for selecting a refresher training course. Only select an option in Question 2 if you need to renew your human subjects protections training.
- If you selected a Group in Question 1, leave Question 2 blank.
 - If you only need to complete COI training, leave Question 2 blank.

Question 2

If you have already completed a CITI Basic Course and would like to enroll in the Refresher Course, please make the appropriate group selection below.

Choose all that apply

- Biomedical Research Investigators and Key Personnel
- Social & Behavioral Research Investigators and Key Personnel
- Research with Records and/or Specimens Only.
- Staff/Floor Nursing personnel NOT involved with a research protocol requiring Informed Consent training

7. Question 3 is for selecting COI training. If you have never completed COI training, 'Yes' will be the only available option.
If you completed COI training within 3 years, you may uncheck the 'Yes' box.

*** Question 3**

Would you like to take the Conflicts of Interest course?


Choose one answer

Yes

8. Click Submit.

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9. This will lead you back to the home page. Click on 'Fairview Health Services' and click on the title on the course to start it.



The screenshot shows the CITI PROGRAM interface. At the top, there is a navigation bar with the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative at the University of Miami". A search bar labeled "Search Knowledge Base" is on the right. Below the navigation bar, there is a "Main Menu" section with a green checkmark and the message "Your request has been successfully submitted." Below this, there is a "DEMO Courses" section with a dropdown menu for "Fairview Health Services Courses". A table below the dropdown shows course details:

Course	Status	Completion Report	Survey
Conflicts of Interest	Passed 09/10/2012	Print Report	Take Survey

Notes:

- You may save your progress if you are unable to complete the training in one sitting.
- Once you complete the course, your completion certificate will be automatically emailed to Fairview Research Administration. You can access a copy of your completion certificate at any time by clicking the 'Print Report' link in course menu.

Please contact Fairview Research Administration at research@fairview.org or (612) 672-7690 with questions.