

VA Requirements for Human Subjects Protection and Good Clinical Practices Training

January 2007

The Office of Research & Development (ORD), Department of Veterans Affairs (VA), Washington DC, **requires annual training in BOTH the protection of human subjects in research and Good Clinical Practices (GCP).**

ORD and the University of Miami's [Collaborative IRB Training Initiatives \(CITI\)](http://www.citiprogram.org) [www.citiprogram.org] have developed a VA training curriculum to satisfy **BOTH** of these annual training requirements. This VA training curriculum includes three courses that build upon each other over three years:

1. A Basic Course for those who have **never taken the VA basic course** on Human Subjects Protections (HSP) and GCP either through CITI or through the VA Employee Education System (EES). [EES no longer hosts HSP/GCP training after December 2006].
2. CITI 101 Refresher Course consists of a number of short modules for those who have taken the VA basic course.
3. CITI 201 Refresher Course for those who have completed the 101 Refresher Course [available next year]

With the new CITI format, you can now register yourself as belonging to multiple facilities [e.g. your local VA facility and an affiliate institution (the University of Louisville)]. If your multiple facilities have overlapping requirements, you will be able to complete the modules just once to get credit toward certificates of completion for all of your facilities. Also, CITI will keep track of your expiration dates and email you when you are due to renew your training.

You will have access to previous training and certificates that you have taken with CITI. All CITI certificates of completion earned between March 2004 and December 2006 are accessible in the new software, and records of any modules completed in the past are transferred and credited in the new software.

The following pages of information are provided to help decide which of the CITI courses need to be completed for VA Researchers and VA research staff AND to help you through the multiple institution registration process. The examples show how an individual who already has a University of Louisville sign-on access can add the VA required training curriculum to their existing CITI access account.

CITI Main Menu - Microsoft Internet Explorer provided by VAMC Louisville

Address: https://www.citiprogram.org/members/mainmenu.asp?stfKeyID=1A94AC3C-46B8-4166-9E8C-3E52DA1586FB-639300

Learner's Menu

[View/Change learner groups](#)

- This is the e-mail address we have for you: _____. If this is not correct, please edit or change your address now.
- You are affiliated with **1 participating institution(s)** on the CITI website. You will have a least one **grade book** per institution to track your progress in meeting the institution's coursework requirements (see below).

Choose: **Affiliate with another institution to add the VA**

[Affiliate with another institution](#) / [Change username or password](#) / [CME/CEU credits](#)

University of Louisville (ID: 410) [View/Change learner groups](#)

You have completed the following coursework for **University of Louisville**. If you would like to take additional modules in one of the curricula, click on a link below.

Human Research Curriculum: [Additional Modules](#) (ID: 4576)

University of Louisville Learner Utilities

- Review [University of Louisville instructions page](#)
- Update profile information for [University of Louisville](#)
- View completed modules
- View course completion history for [University of Louisville and print completion certificates](#)
- Completion Reports from 5-2004 to 12-2006
- Remove my [University of Louisville affiliation](#)

Researchers and research staff who are involved in research at BOTH UofL and the VA MUST complete the training requirements of BOTH institutions.

To meet the VA requirements, at least VA Learner Group 1 (VA GCP Only), MUST be completed in addition to the UofL training requirements.

Researchers and research staff who are involved in research ONLY at the VA are only required to complete the institutional requirements of the VA.

One of the following MUST be completed:
Learner Group 2
 (GCP + Biomedical)
OR
Learner Group 4
 (GCP + Social/Behavioral)

Researchers and research staff who are involved in BOTH Biomedical and Social/Behavioral Research should also complete **Group 3 (Biomedical without GCP) **or Group 5** (Social/Behavioral without GCP)**

CITI Registration Select Institution - Microsoft Internet Explorer provided by VAMC Louisville

Address: https://www.citiprogram.org/members/selectinstitution.asp?stKeyID=0BB933535EEB-48B2-8C8E-95E0C2C5ED70-639300

Wednesday, January 17, 2007

CITI Course in The Protection of Human Research Subjects

[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu](#) | [Logoff](#)

Select your institution or organization

Choose your institution from the appropriate dropdown menu then click **SUBMIT**. If you are affiliated with more than one institution, you will be able to select additional institutions after providing the information required by this institution.

Participating Institutions:

Veterans Affairs:

Department of Energy:

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Start | Person... | Micro... | Adobe... | MIRB2... | Training... | Resear... | CITI ... | 3:08 PM

ADD the Louisville VA to your CURRENT UofL CITI access

CITI Member Information - Microsoft Internet Explorer provided by VAMC Louisville

Address: https://www.citiprogram.org/members/editmemberinformation.asp?stKeyID=FE51EBB6-C447-4CC8-AF4F-0B1FB8F95931-639300

CITI Course in The Protection of Human Research Subjects

[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu](#) | [Logoff](#)

Member Information - Louisville, KY-596

Please provide the following information requested by **Louisville, KY-596**. Required fields are marked with an asterisk.

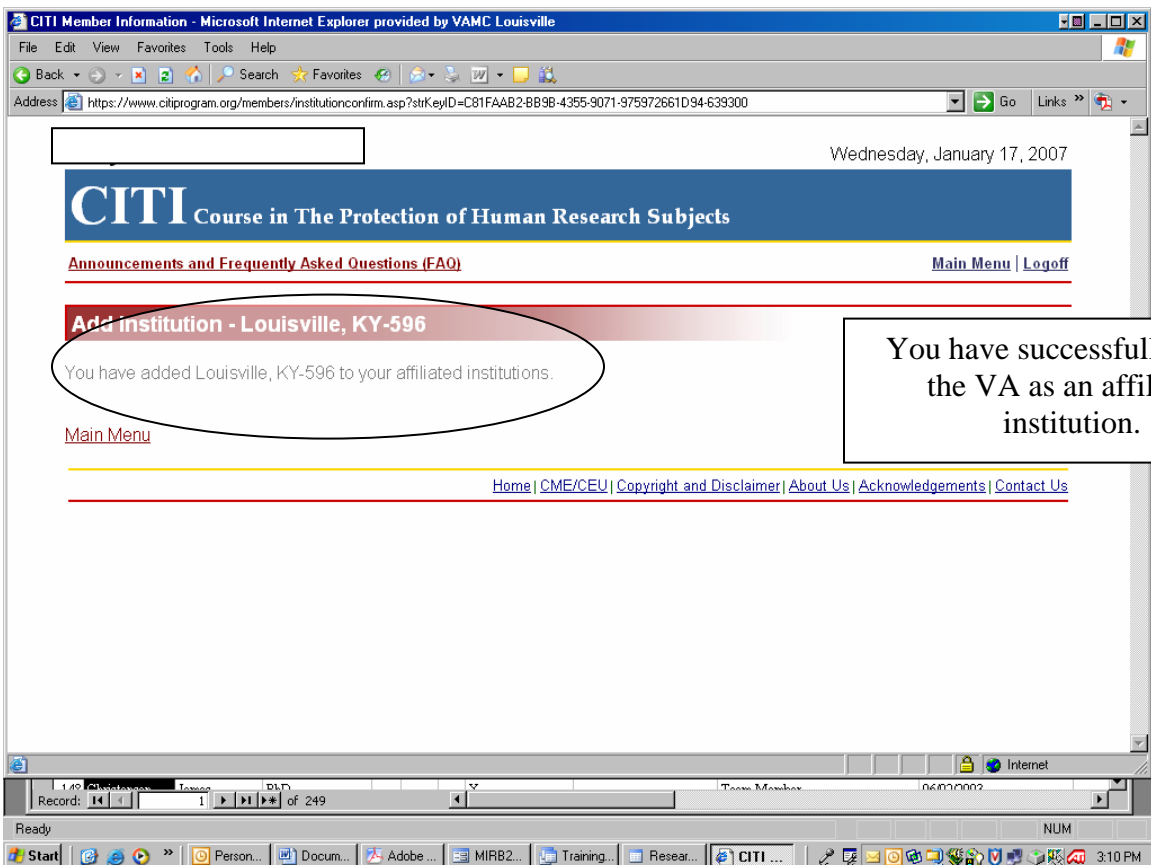
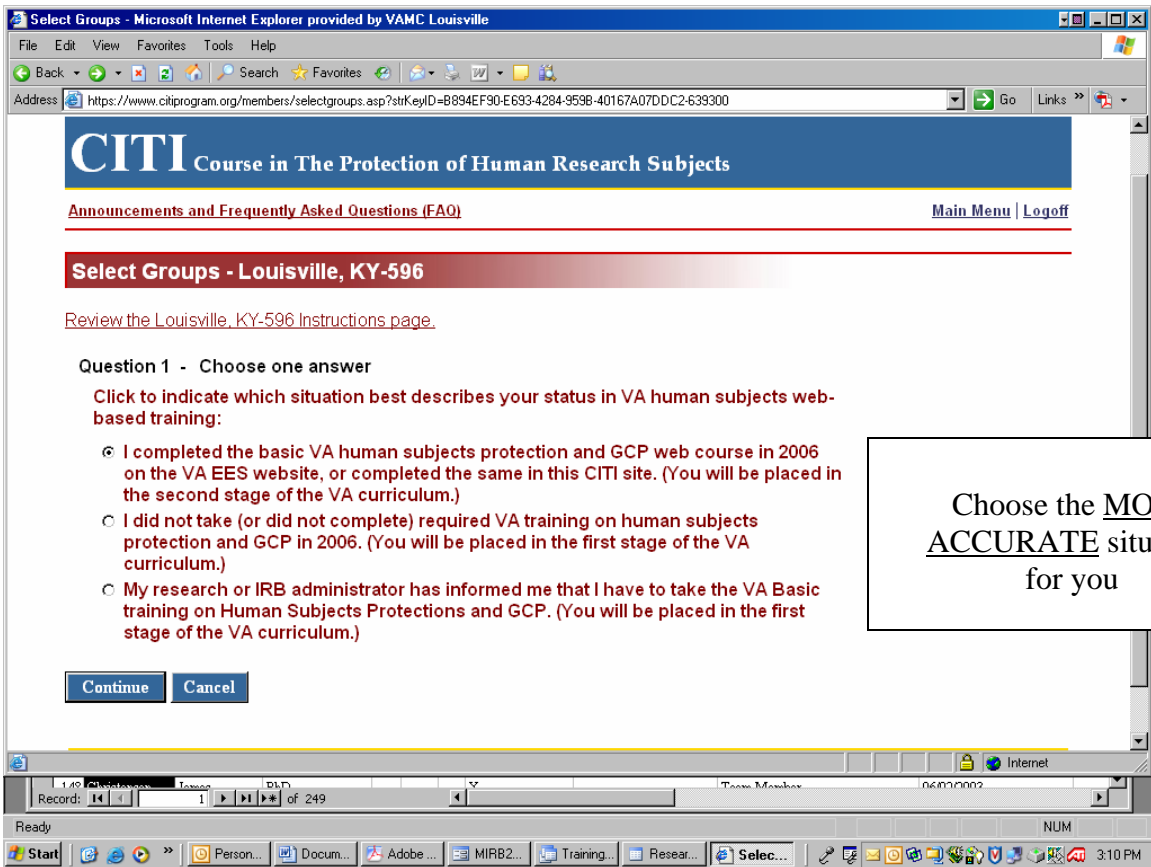
* Gender:	<input type="text" value="Female"/>
* Highest degree:	<input type="text" value="PhD"/>
Employee Number:	<input type="text"/>
* Department:	<input type="text" value="Research"/>
* What is your role in research?:	<input type="text" value="IR"/>
Address Field 1:	<input type="text" value="VA Medical Center"/>
Address Field 2:	<input type="text" value="800 Zorn Avenue"/>
Address Field 3:	<input type="text"/>
City:	<input type="text" value="Louisville"/>
State:	<input type="text" value="KY"/>
Zip/Postal Code:	<input type="text"/>

Record: 1 of 249

Start | Person... | Docum... | Adobe... | MIRB2... | Training... | Resear... | CITI ... | 3:09 PM



Complete the required fields marked with an asterisk (*)



CITI Main Menu - Microsoft Internet Explorer provided by VAMC Louisville

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CITI Course in The Protection of Human Research Subjects

[Announcements and Frequently Asked Questions \(FAQ\)](#) [Main Menu](#) | [Logoff](#)

Learner's Menu

- This is the email address we have for you: [change your address now.](#)
- You are affiliated with 2 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 username or password](#) | [CME/CEU credits](#)

Note that you can now track your training progress at both institutions.

CITI Main Menu - Microsoft Internet Explorer provided by VAMC Louisville

Address: https://www.citiprogram.org/members/mainmenu.asp?stfKeyID=1A94AC3C-4AB8-4166-9E8C-3E52DA15B6FB-639300

Louisville, KY-596 (ID: 179)

Louisville, KY-596 REQUIRES that you complete the coursework listed below. Click on a **Grade Book** link to begin a course.

Human Research Curriculum: [Grade book](#) (ID: 3760)

Louisville, KY-596 Learner Utilities

- [Review Louisville, KY-596 instructions page](#)
- [Update profile information for Louisville, KY-596](#)
- [View completed modules](#)
- [View course completion history for Louisville, KY-596 and print completion certificates](#)
- [Completion Reports from 5-2004 to 12-2006](#)
- [Remove my Louisville, KY-596 affiliation](#)

[View/Change learner groups](#)

University of Louisville (ID: 410)

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Human Research Curriculum: [Additional Modules](#) (ID: 4576)

University of Louisville Learner Utilities

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- [Completion Reports from 5-2004 to 12-2006](#)
- [Remove my University of Louisville affiliation](#)

[View/Change learner groups](#)

You MUST complete **at least VA Learner Group 1**, in addition to the UofL training requirements. (Choose View at each institution to see learner groups.)

Copies of the completion reports for each institution must be submitted to the VA R&D Office