CITI Instructions GCP for Clinical Trials with Investigational Drugs & Medical Devices (FDA Focus) Course

These are the instructions for registering for the GCP Course. This course may be a sponsor requirement for certain clinical trials. The educational course utilized by Marshall University is the Collaborative Institutional Training Initiative (CITI). The steps for completing the educational requirements can also be found on the ORI educational website at http://www.marshall.edu/ori/human-subject-research/education/. The course is broken down into approximately 25 minute modules so you can complete the modules as time permits. The directions for registering for the course are as follows:

<u>Note:</u> There are two separate sets of instructions on this page for the CITI course. One set of instructions are for those who <u>are not</u> currently registered on the CITI site and the other set of instructions are for those who <u>are already</u> registered on the CITI site and simply need to add the GCP Course to their existing profile.

I. Instructions for those not already registered on CITI:

- 1. Go to the CITI Program website at https://www.citiprogram.org.
- 2. The first time you visit the CITI website you will have to register on the site. You do that by clicking on the "Register" link next to the login button. Once you register you will just login each time you return using your established username and password.
- 3. On the first page under "Select Your Organization Affiliation" type in Marshall University and when it appears click on the name. You will then be asked to agree to the Terms of Service for the CITI program. Click the box. You will also be asked to affirm that you are affiliated with Marshall University, and you will need to click that box. Click "Create a CITI Program account".
- 4. You are now on the Learner Registration page. You must complete all fields with an asterisk (*). It is recommended that you also provide a secondary email address in case you lose the ability to access your primary account. Click "Continue To Step 3".
- 5. You are now on another Learner Registration Page. You must complete all fields with an asterisk (*). When finished click "Continue To Step 4".
- 6. In this step you must enter your Country of Residence and skip the Connect your ORCID iD question. Enter "USA" and select "United States". The bottom question asks if you can be contacted later for information about other courses and services. Make your choice and then click "Finalize Registration".
- 7. The next page asks about CE credits. You should select "No" for this question or you will be charged for the courses. Click "Submit".
- 8. On this page you must complete all fields with an asterisk (*). Then click "Next".
- The next page is the "CITI Course Enrollment Procedure" page. You must scroll down the page to view the course selections:

<u>Note:</u> There are several separate questions on this page. Go to <u>Question 7</u> and choose the GCP for Clinical Trials Course. Click on "Submit" at the bottom of the page.

- 10. Now you are registered and should be on the Main Menu page. There you can begin your course by clicking on the course title. You will note that before you can begin your first course you must complete the Integrity Assurance Statement.
- 11. You must have an overall score of 80% to pass the course.

You will not have to go through all these steps each time you go to the site. After the initial registration you will simply login with your Username and Password and pick up where you left off.

II. Instructions for those already registered on CITI:

- 1. Go to the CITI website at https://www.citiprogram.org/. Log in using your previously established username and password. If you have forgotten this information you can click on "Forgot Password" and the system will email this information to you.
- 2. Once logged in you will be on the My Courses page.
- 3. Click on the link halfway down the page out beside Marshall University that says "View Courses".
- 4. This will take you to a page titled "Marshall University". You must scroll down the page to view Active Courses, Courses Ready to Begin, and Completed Courses. If you see the GCP Course under the Courses Ready to Begin, then click on it and start the course. If the GCP Course is not there, then continue with these instructions.
- 5. At the bottom of the current page is a box titled "Learner Tools for Marshall University".
- 6. Click the link to Add a Course.
- The next page is the "CITI Course Enrollment Procedure" page. You must scroll down the page to view the course selections:

<u>Note:</u> There are several separate questions on this page. Go to <u>Question 7</u> and choose the GCP for Clinical Trials Course. Click on "Submit" at the bottom of the page.

Now you are registered for the GCP Course and should be back on the Main Menu page. There you can begin your course by clicking on the title of the course.

If you have any problems or questions, you can contact the Office of Research Integrity (ORI) at 696-4303 or email ori-irb@marshall.edu.

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