

Guidance

Human Subject Research Protections Training Requirements

Children's Wisconsin Human Research Protection Program (Children's HRPP) requires individuals involved in the design, conduct, or review of human subject research to have current Human Subject Research Protections training. This includes any individual involved in research and listed as part of the study team. HRPP Analysts also have Human Subject Research Protections training. Children's utilizes the Collaborative Institutional Training Initiative (CITI) Program to administer such trainings.

The purpose of this training is:

1. **Responsible Conduct in Research:** to assure a thorough and universal foundation in the ethical and legal principles guiding human participant research.
2. **Scientific Integrity:** to enhance the awareness of and sensitivity to research integrity issues such as conflict of interest.
3. **Public Duty:** to demonstrate to project subjects, the community, and research sponsors that we have the training and expertise necessary to protect the rights and welfare of research subjects.

CITI Program website: <https://about.citiprogram.org/en/homepage/>

To access the appropriate courses, affiliate with the Medical College of Wisconsin in your CITI account.

Initial Certification

- Initial CITI Certification is obtained by completing the required online course modules with an overall score of 80%.

Refresher Certification

- In order to maintain CITI certification, everyone is required to complete the CITI Refresher course every three (3) years after initial certification is obtained.

Available Courses

- **Biomedical Research with Good Clinical Practice (FDA focus)**
- **Biomedical Research**
- **Social Behavioral Research**

Guidance

Human Subject Research Protections Training Requirements

Users should select the course most appropriate to the research they will be conducting. For example, if conducting biomedical research, this course should be taken; if doing social/behavioral research, then this course should be taken.

During local context review, CW HRPP may identify that an individual's current CITI training is not sufficient for the particular type of research under review. For example, a researcher with social behavioral CITI training is now conducting an FDA-regulated clinical trial. That individual will be required to also complete the course Biomedical Research with GCP FDA focus.

Contact the Children's HRPP Office at CWHRPP@childrenswi.org if you have any about questions about which courses to complete.

CITI Training Requirements for Study Staff from Other Institutions

If a collaborating individual from another institution is otherwise engaged in research being conducted at Children's but all of that individual's research activities are taking place at the collaborating institution, we will accept their home institution's training requirements.

The following are required to meet Children's training requirements outlined in this guidance document:

- Individuals leaving a former institution and hired on as new staff at Children's/MCW
- Collaborating individuals from outside institutions who will be conducting research activities within Children's/MCW *

*Note: if any of the modules completed at another institution are the same as those required by the relevant Children's Wisconsin course outlined above, these will be credited when the individual associates their profile with MCW. Caveat: CITI determines whether a particular module completed at another institution can be credited by the module ID number. The ID # of the MCW module and the module taken elsewhere need to match. Sometimes, the module title will be identical, but the module may have been revised or changed by CITI so it is given a new ID # and is considered a different module. Additionally there is a "look back" of 3 years on some of the courses. In these cases, if the course was completed someplace else more than 3 years ago, the system will not give

Guidance

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credit for completion. The result is that while some of the modules completed elsewhere will be credited when taking the MCW course, some users may have more to do than others depending on these factors. It is still expected that anyone listed on the study team completes the MCW CITI course appropriate to the study.