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 overseen by the Children's Institutional Review Board (IRB) to have current Human Subject Research Protections training. This includes any individual involved in research and listed as part of the study team. Research Reviewers 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 modules, affiliate with the Medical College of Wisconsin in your CITI account.

Initial Certification

- Initial CITI Certification is obtained by completing the required online 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.

Required Courses

In general, users should select the module most appropriate to the research they will be doing. For example, if doing biomedical research, this module should be taken; if doing social/behavioral research, then this module should be taken (see the table on the following page for more information).

If the individual may potentially be involved in various types of research (both biomedical and social/behavioral) then **Learner Group 3** should be selected.

CITI Modules recognized by Children's Wisconsin

Learner Group 3	Biomedical Research with Good Clinical Practice	Biomedical Learner Group	Social/Behavioral Learner Group
Recommended to fulfill all basic training requirements. The Learner Group 3 module is recommended to satisfy most requirements. This module meets Children's requirements for those who may engage in **both** types of biomedical and social/behavioral research.	Recommended for those only involved in biomedical research. This module is recommended instead of the biomedical learner group because any future requirements for Good Clinical Practice will be already met. Required when the research is an FDA regulated clinical investigation and/or a clinical trial per HHS (National Institutes of Health). This module combines the Biomedical Research modules along with the Good Clinical Practices (US FDA focus) module. Completion of this course will assist investigators and study teams in complying with Sponsor, or Children's departmental/division research requirements.	Minimum requirement for those only involved in biomedical research. Biomedical involves all types of clinical research studies, including FDA-regulated research and those that involve investigational drugs, biologics, and devices. Investigational devices encompass a wide variety of items. The following are examples which would be considered investigational devices: • Non-FDA cleared devices (both implantable or applied to the surface of the body) • Investigational software which will be run on a FDA cleared device (such as WIP MR pulse sequences, or post-processing analysis); • In-vitro diagnostic assays (IVD), laboratory developed tests (LDTs); • Certain types of mobile applications which may provide a clinical decision	Required for those only involved in social/behavioral research. Social/Behavioral Research (SBR) encompasses a wide variety of research including but not limited to: • Observational, • Survey research, • Epidemiological studies This type of research does not involve any drugs or devices (investigational or market-approved). If the individual will be involved in **both** biomedical and social behavioral research, it is recommended they take the Learner Group 3 module.

Other Courses that May be Required in Addition to the Above

Good Clinical Practice for Social Behavioral Research	Good Clinical Practice	Conducting Research Responsibly (RCR)
Required when the research is social behavioral research and FDA regulated clinical investigation and/or a clinical trial per HHS (National Institutes of Health). This course is a stand-alone GCP course with a focus on social/behavioral research.	Required when the research is an FDA regulated clinical investigation and/or a clinical trial per HHS (National Institutes of Health). This course is a stand-alone GCP course to be taken if GCP training is required and it was not previously taken in combination with appropriate Biomedical modules.	This course is only required if the IRB determines that it will be part of a preventative action plan for non-compliance. This course should not be used to fulfill the CITI training requirement for investigators or others on the research team that are conducting research.

Courses for Learner Groups 6, 7, 8, 9, 10 are for more specific situations. Contact the Children's IRB Office at CHWIRB@chw.org if you have any about questions about which modules to complete.

CITI Training Requirements for Study Staff from Other Institutions

If an individual from another institution is otherwise engaged in research 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.

Those who are conducting research activities **and** who Children's requires to be current with and take the **Children's/MCW** CITI training (even if they completed CITI training at another institution) include:

- 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 *

*However, if any of the modules completed at another institution are the same as those required by the MCW/CHW course, these do not need to be taken again and would 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 credit for completion. The result is that while some of the modules completed elsewhere will be given credit when taking the MCW course, some users may have more to do than others depending on these factors. However, it is still expected that anyone listed on the study team completes the MCW CITI course appropriate to the study.