MHC IRB Training Requirements

Required Training for All Key Study Personnel

Basic Human Subjects Research (HSR) Course

All Key Study Personnel at McLaren Health Care must complete human subjects protection training on the Collaborative Institutional Training Initiative (CITI) website. The requirement to complete CITI training applies to Key Study Personnel on all Human Subjects Research including Exempt, Expedited and Full Board studies. IRB approval of any individual application is contingent upon the fulfillment of this requirement.

MHC Definition of Key Study Personnel (KSP)
Key Study Personnel (KSP) include the Principal Investigator, other investigators and research personnel engaged in the conduct of the research activity such that they directly intervene or interact with human subjects with research participants to obtain consent and/or research data or will have access to participants' private and identifiable private information during data collection or data analysis. ------- Key Personnel also include faculty mentors/Academic Advisors who provide direct oversight to Postdoctoral Fellows, Residents and Clinical Fellows on the IRB application.

There are two educational tracks for the Basic Human Subjects Research Course:

- **Biomedical (Biomed)**
- **Social-Behavioral-Educational (SBE)**

To receive maximal benefit, you should choose the track most closely related to the research in which you are involved. Each track contains up to sixteen required modules which take approximately 10 to 30 minutes to complete, as well as several optional modules. The Human Subjects Research training is valid for a 3-year period, after which time a Refresher Human Subjects Research Course must be completed.

***Important Note**: CITI Human Subject Research training course taken under a non-McLaren Health Care institution may be accepted. However, we will require affiliation* with McLaren Health Care on the CITI website. CITI will review the modules previously completed and the date(s) taken. CITI will ask the individual to complete any modules required by McLaren Health Care that were not required by your previous institution.*

**Step-by-step instruction on how to affiliate or link to MHC CITI can be found on the Research Integrity Department website at https://www.mclaren.org/main/required-training-citi under frequently asked questions.*

Additional Training

Conflicts of Interest Course

In addition to HSR training, all investigators and academic/faculty advisors must complete the CITI Conflicts of Interest Course. This training is valid for a 4-year period.

Good Clinical Practice Course

If your clinical trial is required to adhere to ICH-GCP E6 guidelines, you must complete Good Clinical Practice (GCP) training. *GCP training is an additional separate training and is not basic human subjects protection training.* GCP principles are specific to clinical trials and include international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials. Refer to clinical trial contract/agreement, sponsor or funding agency to determine if your research protocol is required to adhere to ICH-GCP E6 guidelines. Individuals engaged in the conduct of a clinical trial (per the NIH definition) must complete a Good Clinical Practice (GCP) training. CITI GCP course options in CITI course are:

- **Good Clinical Practice for Clinical Trials with Investigational Drugs and Biologics (US FDA Focus)**.
- **Good Clinical Practice Social and Behavioral Best Practices for Clinical Research**
- **GCP for Clinical Investigations of Devices** *(formerly called GCP Course for Clinical Trials Involving Investigational Medical Devices (international focus)*
- **GCP for Clinical Investigations of Drugs and Biologics (ICH)** *(formerly called GCP for Clinical Trials Involving Investigational Drugs (international / ICH focus)*

Good Clinical Practice training is valid for a 3-year period, after which time a Refresher GCP Course must be completed. Alternative GCP training review - Submit a request for acceptance of alternate GCP training in lieu of the options above and email documentation of past training. McLaren Health Care IRB will accept GCP training from the following:

- NIH https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm
- Industry sponsors (e.g., organizations, etc. registered with TransCelerate Biopharma Inc.'s GCP Training Mutual Recognition program)
- Federal sponsors (e.g., NIH's NIAID GCP or National Drug Abuse Treatment Clinical Trials Network GCP)

Engaged and Community-Based Participatory Research

Investigators conducting community engaged research must complete the CITI Engaged and Community-Based Participatory Research. For more information about community-based engaged research see our web page https://www.mclaren.org/main/community-engaged-research

For additional assistance you can contact the MHC Research Integrity Department at hrpp@mclaren.org or call248-484-4950