***Research Staff Training***

1. **PURPOSE**

This Standard Practice Guideline (SPG) describes the procedures, processes, documentation, and responsibilities for the completion of educational training by research team members.

(**MANDATORY LANGUAGE**)

1. **SCOPE**

This Standard Practice Guideline (SPG) applies to all research staff, including the Principal Investigator (PI), Co-Investigator(s) (Co-I), Study Coordinator(s), and additional research staff that may be involved in the conduct of the clinical trial.

(**MANDATORY LANGUAGE**)

*[Optional: Insert any additional details necessary to further define the scope of this SPG.]*

1. **POLICY**

**Good Clinical Practices (ICH GCP)**

This Standard Practice Guideline aligns with the Good Clinical Practice (ICH GCP) guidelines established by the International Council on Harmonization (ICH). Section 4.1.1 indicates *The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authorities.*

Furthermore, (ICH) 2.8 (Principles of ICH GCP) indicates *each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks.*

**FDA Regulation(s)** (if applicable)

Per 21 CFR 312.53(a), *A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug.*

Furthermore, CFR 812.43(a) indicates *A sponsor shall select investigators qualified by training and experience to investigate the device.*

**Michigan Medicine**

According to the University of Michigan Human Research Protection Program’s Operation Manual*, Researchers must complete educational training as required by the University, the relevant IRB, and other review units prior to initiating research, and should not undertake responsibility for human subjects studies unless they understand these requirements and are willing to be held accountable for complying with the relevant standards and protecting the rights and welfare of research participants.*

In addition, the University of Michigan requires anyone engaged in or associated with human subjects research to complete the Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) training and ICH-GCP training for study team members engaged in NIH research. Key personnel including principal investigators, co-investigators, faculty advisors, study coordinators, and project managers must complete PEERRS before the IRB can approve a clinical trial. Responsibility for assuring all others complete PEERRS falls to the principal investigator.

**(MANDATORY LANGUAGE)**

**Additional Regulations or Policies** [ ]  **N/A**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

SPONSOR: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI): A public-private partnership to identify and promote practices that will increase the quality and efficiency of clinical trials.

INTERNATIONAL COUNCIL ON HARMONISATION (ICH): A joint initiative involving both regulators and research-based industry representatives of the European Union, Japan, and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality, and efficacy of medicines.

**(MANDATORY LANGUAGE)**

Note: Some of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 01-Oct-2022 and are subject to change. Please see the [IRBMed Glossary](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/glossary) for the most current definitions and additional guidance.

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Practice Guideline that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of PI is ultimately *responsible* for assuring all research team members are adequately trained for their role on the clinical trial. The PI shall be responsible for the following activities:

* Selects research staff qualified by education, training, and experience to assume responsibility for the conduct of the clinical trial
* Completes all required University of Michigan training for clinical trials which may include Mlearning, MiChart, ONCORE, PEERRS, HIPPA and ICH-GCP (CITI or other). This includes any skills required for core competencies for participation in clinical research
* Completes the required, project-specific training necessary for conduct of a clinical trial. For example, if the study is recruiting minors, complete Minors as Research Participants eLearning course
* Ensures adequate research specific training which may include Mlearning, MiChart, PEERRS, HIPAA, ICH-GCP, and if applicable as well as any required project-specific training, has been completed for all clinical research staff associated with the clinical trial prior to the enrollment of subjects
* Ensures adequate documentation of training and education of investigators and other research staff
* Provides additional training, as appropriate, to accommodate amendments to the protocol, staffing changes, changes in technology, etc.
* Delegates responsibilities where appropriate

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee*]

**Study Coordinator(s)/Designee**

An individual filling this role may be responsible for the following activities:

* Completes all required University of Michigan training for clinical trials to fulfill his/her role on the clinical research team. This may include Mlearning, MiChart, ONCORE, PEERRS, HIPPA, and ICH-GCP. Also included are any skills required for core competencies for participation in clinical research
* Completes the required, project-specific training necessary for conduct of a clinical trial
* Maintains and stores required educational certifications, licensures and other training requirements associated with the roles and responsibilities assigned to research team members
* Completes additional and requalification training, as applicable
* Communicates concerns regarding clinical research staff training to the attention of the Principal Investigator or designee

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee*]

**Co-Investigator(s)**

An individual filling this role may be responsible for the following activities:

* Completes all required University of Michigan training for clinical trials to fulfill his/her role on the clinical research team. This may include Mlearning, MiChart, PEERRS, HIPPA, and ICH-GCP. Also included are any skills required for core competencies for participation in clinical research.
* Completes the required, project-specific training necessary for conduct of a clinical trial
* Completes additional and requalification training, as applicable

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Co-Investigator]*

**Additional Roles and Responsibilities** [ ]  **N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SPG]*

1. **PROCEDURE**

**Protocol Training**

*[Describe the process used to train research staff on the clinical trial protocol]*

**Clinical Trial Procedures Training**

*[Describe the process used to train research staff on how to perform clinical trial procedures]*

**Clinical Research Training**

*[Describe the process used to train research staff on the required core competencies for clinical research]*

**Documentation of Training**

*[Describe the process used in documenting training(s) of research staff, including maintenance and storage of documentation (*i.e*., CVs, PEERRS, HIPAA, Shipping of Infectious Substances &*

*Patient Specimens**and* ***Annual Bloodborne Pathogens, venipuncture, core competencies, etc.****)]*

**Additional Procedures** [ ]  **N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

MICHR Resources - Study Management Templates:

<https://michr.umich.edu/resources/study-management-templates?rq=templates>

University of Michigan - Institutional Review Boards (IRBMED):

<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed>

University of Michigan - IRB Collaborative Online Educational Presentations (UMIC):

<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/u-mic-0>

University of Michigan - Office of Research - IRBMED Education:

<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/education>

University of Michigan - Mlearning:

<https://trainingportal.med.umich.edu>

University of Michigan - Michigan Institute for Clinical and Health Research - Education Training Mentoring:

<https://www.michr.umich.edu/rdc?category=Education+%26+Training>

University of Michigan - Occupational Safety and Environmental Health Course List - Shipping of Infectious Substances/Patient Specimensand **Annual Bloodborne Pathogens:**

<http://ehs.umich.edu/research-clinical/biological/transporting-biological-materials/>

University of Michigan - Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS):

<http://my.research.umich.edu/peerrs/>

University of Michgian – Research with Minors Training: <https://childrenoncampus.umich.edu/resources/research/>

University of Michigan - Research and Ethics & Compliance Human Research Protection Program Operations Manual:

<http://research-compliance.umich.edu/human-subjects/operations-manual-contents-page>

Consortium of Academic Programs in Clinical Research:

<https://mrctcenter.org/wp-content/uploads/2016/02/2014-06-Moving-from-Compliance-to-Competency-CenterWatch.pdf>

Consortium of Academic Programs in Clinical Research:

<https://coapcr.org/>

FDA Title 21 CFR 312.53 - Selecting Investigators and Monitors-Investigational Drug:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=dd0ce9060f6135c6ffc5fbc8e5189fef&mc=true&node=se21.5.312_153&rgn=div8>

FDA Title 21 CFR 812.43 - Selecting Investigators and Monitors-Investigational Device:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=119&SID=5b79c575275c2aa91f15b79964501546&ty=HTML&h=L&mc=true&n=pt21.8.812&r=PART#se21.8.812_143>

International Council for Harmonisation

<http://www.ich.org/>

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

HHS Office of Human Research Protections (OHRP) Guidance:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/>

NIH Office of Clinical Research and Bioethics Policy, Clinical Research Policy:

<http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy>

NIH policy for ICH-GCP training:

<https://grants.nih.gov/grants/guide/notice-files/not-od-16-148.html>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SPG references]*

1. **APPENDICES**

*[Optional: Insert any additional SPG appendices]*