***Research Staff Training***

1. **PURPOSE**

This Standard Operating Procedure (SOP) describes the procedures, processes, documentation, and responsibilities for the completion of educational training by research team members.

(**MANDATORY LANGUAGE**)

1. **SCOPE**

This SOP 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 SOP.]*

1. **POLICY**

Good Clinical Practices (GCP) guidelines established by the International Conference 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 ☐ N/A

*[If this SOP is not intended for FDA regulated clinical trials, check the N/A box]*

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.*

University of Michigan

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. 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.

**(MANDATORY LANGUAGE)**

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

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of PI is responsible for making sure 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 including Mlearning, MIChart, PEERRS, HIPPA and any training required for clinical research teams under the jurisdiction of the Clinical Trials Transformation Initiative (CTTI). 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
* Ensures adequate research specific training including Mlearning, MIChart, PEERRS, HIPAA, and the Clinical Trials Transformation Initiative (CTTI) 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.

**(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 includes Mlearning, MIChart, PEERRS, HIPPA and any training required for clinical research teams under the jurisdiction of the Clinical Trials Transformation Initiative (CTTI). 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 includes Mlearning, MIChart, PEERRS, HIPPA and any training required for clinical research teams under the jurisdiction of the Clinical Trials Transformation Initiative (CTTI). 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 SOP]*

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**

**University of Michigan References**

Study Coordinator Website - Study Management Tools:

<http://www.umstudycoordinators.org/study-management-templates/>

University of Michigan - Biomedical Institutional Review Boards (IRBMED):

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/education-0>

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

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/u-mic>

University of Michigan - Office of Research - IRBMED Education:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/education-0>

University of Michigan - Mlearning:

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

University of Michigan - Mlearning - Mandatories: <http://mlearn.sites.uofmhosting.net/mandatories/>

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

<http://www.michr.umich.edu/education>

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

<http://www.oseh.umich.edu/pdf/CourseList.pdf>

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

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

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

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

**Non-UM References**

TheClinical Trials Transformation Initiative (CTTI):

<http://www.ctti-clinicaltrials.org/home>

Consortium of Academic Programs in Clinical Research:

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

Consortium of Academic Programs in Clinical Research - Moving from Compliance to Competency:

A Harmonized Core Competency Framework for the Clinical Research Professional:

<http://www.coapcr.org/wp-content/uploads/2014/10/Clinical-Research-Competencies.pdf>

Consortium of Academic Programs in Clinical Research - Domains of Proficiency and Areas of Competency to be Utilized in the Development of Core Curricula for Academic Programs in Clinical Research:

<http://www.coapcr.org/wp-content/uploads/2014/03/COAPCR-Domains-and-Competencies-October-29-2012.docx>

FDA Title 21CFR 312.53(a), Selecting Investigators and Monitors-Investigational Drug:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.53>

FDA Title 21CFR 812.43(a), Selecting Investigators and Monitors-Investigational Device:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.43>

International Conference on Harmonisation (ICH):

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

International Conference on Harmonisation (ICH) - Glossary:

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

HHS Office of Human Research Protections (OHRP) Guidance:

<http://www.hhs.gov/ohrp/policy/index.html>

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>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

*[Optional: Insert any additional SOP appendices]*