Title: Core Standard Operating Procedure for Training

I. Procedure Statement
To describe the processes, responsibilities, and documentation requirements related to the training of all research personnel involved in a research study.

II. Definitions
1. Research Level 1 training: Per SOM-R-003 policy, any research staff member (or resident/fellow serving in a research staff role) is required to have a demonstrated proficiency for engaging in research involving human participants prior to being placed on an IRB approved study. This includes conceptual knowledge of human research regulations.
2. Research Level 2 training: Per SOM-R-003 policy, any research staff member (or resident/fellow serving in a research staff role) is required to have a demonstrated in-depth technical knowledge of human research to an extent that will allow for an appropriate degree of autonomous functioning commensurate with educational level, position description, and professional responsibility.
3. Investigator training: Per SOM-R-003 policy, to be privileged at the Investigator level, comprehensive knowledge of human research regulations and guidelines at both the conceptual and technical levels must be demonstrated. In addition, educational credentials (typically at the doctoral level) will be required in areas commensurate with the proposed research.
4. Study Initiation training: Training provided by a sponsor at either (a) off-site multi-center investigators’ meeting, (b) on-site at a site-initiation visit, (c) online training modules, or (d) a combination of any of these methods.
5. Protocol specific training: Training which includes study specific protocol details and duties which are required of sub-investigators, physicians and staff that will be involved in study related procedures (includes ancillary units) and falls under the responsibility of the Principal Investigator.

III. Procedure/Content/Scope
This SOP will apply to all clinical trials research within MU Health including the School of Medicine, School of Health Professions, School of Nursing, and MU Healthcare. This SOP will outline the processes that should be followed to ensure all personnel involved with research study activities are appropriately trained.

1. Prior to being added as study personnel on an IRB project, study specific staff (including residents/fellows serving in a research staff role) must meet the minimum Research Level 1 or Level 2 criteria relative to their role in the study.

2. Additional training of study personnel is the responsibility of the PI. Certain protocol specific training may be delegated by the PI to approved study personnel but the PI should oversee training activities and is ultimately accountable. Documentation of protocol specific training must be timely (prior to subject enrollment), documented and
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maintained in the study binder. Training should include:

a. Ancillary and support departments such as Diagnostic Imaging; Radiation Therapy; Investigational Pharmacy Services; Clinic and Infusion Nursing, Pathology/Lab, Respiratory Therapy, and other therapy and ancillary services as identified should receive training specific to the areas of the protocol that pertain to them. In addition, any study specific forms that are to be completed by these areas should be reviewed in detail with a focus on any time and marker parameters required for inclusion/exclusion criteria.

b. Research personnel will actively discuss all aspects of the trial including trial objectives, delegation of authority, eligibility criteria, recruitment strategies, protocol procedures, special testing, documentation requirements, Adverse Events (AE) and Serious Adverse Events (SAE) reporting, Case Report Form (CRF) completion, and monitoring plan.
   a. Research personnel should be familiar with the purpose of the study and the specific protocol; have adequate understanding of the details of the protocol relative to their assigned duties in trial conduct; be qualified by education, training, and experience to perform tasks that have been delegated; and receive additional training as appropriate when changes are made to the protocol or trial conduct. Refer to Core SOP for post-award amendments. (Appendix G).

3. Documentation of all training must be maintained in the study binder and available for review by sponsors or regulatory representatives and should include the signature of the PI or appropriately designated trainer.

4. Protocol specific training should be considered an ongoing activity responsive to protocol amendments, trial conduct, and staffing turnover.

IV. REFERENCES:

1. SOM-R-003 Training Requirements for Conduct of Research Involving Human Participants.
2. 21 CFR 312.60 General responsibilities of investigators
4. 21 CFR 312.50 General responsibilities of sponsors