SOP#: PM-5	**Research Protocol Training Requirements**
Version #: 1.1	**Next Review Date: 08/2024**
Approved Date: 08/2023	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley Digitally signed by James Gulley Date: 2023.08.10 11:05:16 -04'00'

POLICY

The PI is responsible for ensuring that all study staff working on a research protocol are adequately trained on the protocol, including informed consent and other applicable protocol documents (e.g., Investigator Brochure, manuals, etc.) as required depending on their role in the study. All study staff listed on the delegation log must have protocol training and the training must be documented. Training can take place two weeks prior to or one week after staff "start" date on the delegation log. If the study sponsor has other requirements, this policy does not supersede.

For treatment/intervention protocols (including those that do not have an IND), protocol training first takes place during the site initiation visit (SIV) by the study sponsor, or the study start up meeting conducted by CCR Office of Education and Compliance (OEC). Ideally, all members of the study team should be present to receive this training during this scheduled meeting as their attendance is documentation of training. If someone does not attend the SIV/start up meeting, they must still have protocol training and the training must be documented. For interventional studies, protocol training done after the SIV or study start up meeting must be conducted by the PI or appropriate physician Associate Investigator.

For observational studies that do not have a study start up meeting, members of the research team must still have protocol training and the training must be documented.

Any study staff added to the team after the SIV or study start up meeting must have protocol training and the training must be documented. Training must take place prior to, or on, the new staff "start" date on the delegation log.

PURPOSE

To provide guidance to PIs and research teams related to appropriate protocol training and appropriate documentation.

RESOURCES

- FDA Guidance Document: Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects
- FDA: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
- Office of Intramural Research Policies website
    - 300 – Investigator Responsibilities

PROCEDURES FOR TEAM PROTOCOL TRAINING AND DOCUMENTATION

Site Initiation Visit (SIV) By the Sponsor

The study sponsor is responsible for conducting an SIV prior to the protocol being open for recruitment. All research team members should join the SIV as their attendance will serve as documentation of initial study training. An attendance sheet must be maintained to identify those present at the meeting. All training documents and the attendance sheet must be maintained in the regulatory file. Staff member start date on the delegation log can be the date of the SIV but cannot be prior to the SIV.

Study Start Up Visit by the OEC

All studies sponsored by CTEP and all treatment/intervention protocols that do not involve investigational agents should have a study start up meeting conducted by the OEC. While it is preferred to have this meeting prior to opening the study for recruitment, there could be times when this is not feasible. However, the meeting should take place as early as possible after the study is open. All research team members should join the study start up meeting as their attendance will serve as documentation of initial study training. An attendance sheet must be maintained to identify those present at the meeting. All training documents and the attendance sheet must be maintained in the regulatory file. Staff member start date on the delegation log can be the date of the study start up meeting but cannot be prior to the meeting.

Note: Observational studies are not required to have a study start up meeting, but one can be requested via nciccroec@mail.nih.gov in Global.

Protocol Training for New Staff (or staff not in attendance at SIV/Study Start up Meeting)

Any new staff members that join the team after the SIV/Study Start up meeting must have protocol training. In addition, any staff listed on the delegation log that did not attend the SIV/study start up meeting must also have protocol training. Training must be conducted by the PI or appropriate designee (e.g., lead AI) and documented via the Checklist in Appendix A. The completed and signed checklist must be sent to the protocol PSO manager for uploading into the regulatory file. The checklist may be signed using a PIV signature or “wet” signature.

APPENDIX A

Documentation of Protocol Training

Protocol Number:

Brief Protocol Title:

Principal Investigator:

Name of staff member:

Role in study:

The following items must be reviewed and discussed with the PI/designee as applicable:

Item Reviewed/Discussed	**Date Completed (or N/A)**
Review all Site Initiation Visit slides, if available	
Review current version of protocol [enter version date]	
Review current version of informed consent document [enter version date]	
Review current Investigator Brochure [enter version date]	
Review recruitment materials, if any	
Review Manual of Procedures (MOP), if any	
Review laboratory manual, if any	
Review pharmacy manual, if any	
Review all protocol database(s) and take training if applicable	
Discuss questions and role (on delegation log) with Principal Investigator	

New staff member signature and date: By signing below, I attest that I have reviewed all applicable items/documents related to my role on the study. In addition, I have discussed my role with the PI/designee and all questions have been answered.

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PI/designee signature and date: By signing below, I attest that the staff member has confirmed review of all applicable items/documents related to their role on the study. In addition, I have discussed the staff member's role on the study and all questions have been answered.

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