MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE REQUIRED PROTOCOL TRAINING	
SOP#: 4.1.1	**Original Approval Date: 5/8/13**
Version#: 5.0	**Current revision Date: 11/5/21**

1.0 PURPOSE/BACKGROUND

The purpose of this Standard Operating Procedure (SOP) is to describe the process for completing protocol training.

2.0 SCOPE

This SOP affects all studies that require staff training to be completed for appropriate study conduct.

3.0 RESPONSIBILITY

Study Staff
Investigators
Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

Self-Training: Process by which an individual on the delegation of authority log or associated with the study has read and understands the protocol, IB as applicable, and/or other training materials as well as their role in the trial. This process includes seeking answers to any questions about the conduct of the study from the Principal Investigator, Sponsor, or the appropriate designee.

Ancillary Study Documents: Documents necessary to appropriately conduct a clinical trial. As applicable, these documents include but are not limited to consents, study manuals, study materials, and study measures.

5.0 ROLES AND PROCEDURES

Study Sponsors:

5.1 Sponsors must clearly outline expectations for specific study staff training requirements for the duration of the study prior to protocol activation.

5.2 Sponsors must provide documentation of completed sponsor-provided training.

Study Staff:

5.3 Only those listed on the Delegation of Authority Log are eligible to complete protocol training.

5.4 Study staff will only complete training that is relevant to their delegated responsibilities on the Delegation of Authority Log. (See *6.2.6.2.3 CCCTO SOP Documenting Delegation of Authority*.)

5.4.1 Regulatory staff will not be required to complete protocol training as they are not executing any study procedures outlined within the protocol.

5.4.2 Investigators will not be required to do training on investigator-initiated studies in which they are the PI, as they are the authors of the protocol and are responsible for the content.

5.5 Training will not be required for studies that are closed to accrual and no subjects are impacted by the amendment or study update.

5.6 The regulatory staff track initial protocol training and substantive updates. Study staff and investigators will be notified of administrative changes, but training will not be tracked. Pertinent study staff will complete study training for the initial version of the protocol on which they are study staff. No training logs will be collected beyond the initial protocol training for studies not housed in the Florence eBinder system. For these studies, email distribution of the protocol document updates is considered notification that self-training is required.

5.7 Studies that are transitioned to or opened using the Florence eBinder system will have self-training documentation acknowledged within the system. These acknowledgements will be available upon sponsor request.

5.8 If a sponsor requires any specific study training beyond review of the updated documents (e.g., webinars, PowerPoint slides, conference calls, etc.), the sponsor must provide this training and track the completion.

5.9 All study staff members will complete Collaborative Institutional Training Initiative (CITI) Human Subject Research training and CITI Good Clinical Practice (GCP) training. Therefore, study staff will not complete sponsor-specific GCP training without approval from a Research Manager.

5.10 CITI Human Subject Research & GCP courses will be renewed every three years.

5.11 Training documentation will be stored and maintained electronically.

6.0 REFERENCES

6.2.6.2.3: CCCTO SOP Documenting Delegation of Authority

7.0 APPENDICES

None

Authorized by:

Signed Electronically by:
Betty Oleson - boleson@mcw.edu
11-Feb-2022 @ 08:46 AM CST Reason: Approval

CCCTO Administrative Director

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Previous Electronic Signatures:

There are no signatures for any previous versions.