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#: 4.0	**Current revision Date: 11/19/19**

1.0 PURPOSE/BACKGROUND

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

2.0 SCOPE

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

3.0 RESPONSIBILITY

Study Staff
Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

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 *6.2.6.2.2 CCCTO SOP Completing the Delegation of Authority Log*.)

5.5 The CCCTO will provide documentation of any internal training provided upon request. The regulatory staff track initial protocol training. Pertinent study staff will complete study training for the initial version of the protocol on which they are study staff. Within that initial training they will acknowledge and accept that they are responsible for self-

training for all future protocol versions upon notification from the study team. No training logs will be collected beyond the initial protocol training.

5.6 Existing studies may be transitioned to this process upon the approval of SOP v4.0, as appropriate.

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

5.8 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.

5.9 If a sponsor requires any specific study training to be completed, the sponsor must provide this training and track the completion.

5.10 All study staff members will complete Collaborative Institutional Training Initiative (CITI) training, which includes Good Clinical Practice (GCP) training. Therefore, study staff will not complete sponsor specific GCP training without approval from a Research Manager.

5.11 CITI & GCP modules will be renewed every three years.

5.12 Training documentation will be stored and maintained electronically.

6.0 REFERENCES

6.2.6.2.2: CCCTO SOP Completing the Delegation of Authority Log

7.0 APPENDICES

None

Authorized by: _____ _____

James Thomas, Medical Director

Betty Oleson, CTO Administrative Director

Revision dates:
5/8/13, v 1.0
3/2/15, v.2.0
2/14/17, v 3.0
11/19/19, 4.0

Review dates:
3/7/14, 3/2/15, 1/8/16, 2/14/17, 2/20/18, 11/19/19, 3/16/20