MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE PLANNED STUDY TRANSITION BETWEEN CTO EMPLOYEES	
SOP#: 6.5.4	**Original Approval Date: 8/21/13**
Version#: 2.0	**Current Revision Date: 2/20/18**

1.0 PURPOSE/BACKGROUND

It is often necessary to transfer study coordinating responsibilities between team members for various reasons. The purpose of this standard operating procedure (SOP) is to define the process for the planned transition of studies between CTO employees.

2.0 SCOPE

This SOP describes the steps to be taken to successfully transfer study responsibilities between CTO employees in planned situations. In unforeseen situations (i.e. an employee's unexpected departure from the CTO, whether permanent or temporary), this SOP would not be applicable.

3.0 RESPONSIBILITY

Study Coordinators
Clinical Research Assistants
Regulatory Staff
Disease Team Leads/Research Managers
Principal Investigators
Study Sponsors or their designees, when applicable

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Additional Definitions:

Former Study Staff Member (Former SSM): The study staff member in need of study to be transferred.

Newly Appointed Study Staff Member (Newly Appointed SSM): The study staff member that will be taking over the duties of the study going forward.

5.0 ROLES AND PROCEDURES

Disease Team Lead/Research Manager:

5.1 The DTL/Research Manager will assign a new staff member to the applicable study in need of transition. This will be communicated to the Newly Appointed SSM.

Former Study Staff Member & Newly Appointed Study Staff Member:

5.2 Former SSM will facilitate the study transition to the Newly Appointed SSM and all necessary training/shadowing.

5.3 Transition and training must be documented. Completion of the Study Transition Checklist (Appendix I) is considered sufficient final documentation of the transition process.

5.4 The Newly Appointed SSM assumes responsibility for the study upon date of signature on the Study Transition Checklist. The Former SSM may provide continued assistance post-transition, as needed.

5.5. Study Transition Checklist should be filed in the training section of the regulatory binder or it may be scanned into the study folder on the I:drive and the original may be discarded.

6.0 REFERENCES

None

7.0 APPENDICES

See Appendix I attached (planned study transition checklist).

Authorized by:

Signed Electronically by:
Betty Oleson - boleson@mcw.edu
11-Feb-2022 @ 08:50 AM CST Reason: Approval

CCCTO Administrative Director

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Appendix I: PLANNED STUDY TRANSITION CHECKLIST

Study Short Title: _____

IRB Number: _____

Principal Investigator: _____

"The following points have been reviewed for the above referenced study for purposes of study transition/training":

- ☐ Notifications
  i.e. Regulatory Staff or Study Coordinator, PI & Treating/Enrolling Physicians, Sponsor contacts and/or Study Monitor, update personnel information in OnCore & eBridge.
- ☐ Regulatory: i.e. Any study specific details regarding regulatory.
- ☐ Study specific training: (study coordinators only) i.e. Schema, eligibility, time & events table, correlatives, sponsor-required training
- ☐ Nursing Tip Sheet contact information updated (study coordinators only)
- ☐ Patients/data (study coordinators only)
  CRFs, FYI Flag, EPIC Research tab, patient binders, next scheduled visit (if on active treatment)
  Oncore calendar, action required on Beacon Treatment Plan

_____	_____	_____
Print (Former Study Staff Member)	**Sign**	**Date**
_____	_____	_____
Print (Newly Appointed Study Staff Member)	**Sign**	**Date***
_____	_____	_____
Print (Research Manager/Lead)	**Sign**	**Date**

**The Newly Appointed Study Staff Member assumes full study responsibility from his/her date of signature.*

Current Electronic Signatures (v.9):

Signed electronically by: Betty Oleson (boleson@mcw.edu)

Date: *11-Feb-2022 @ 08:50 AM CST*

Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.