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#: 4.0	**Current Revision Date: 3/17/25**

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/Disease Team 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/Disease Team Manager:

5.1 The DTL/Disease Team Manager will assign a new staff member to the applicable study in need of transition. This will be communicated to the Newly Appointed SSM and Former 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 regulatory binder or it may be scanned into the electronic study file and the original may be discarded.

6.0 REFERENCES

None

7.0 APPENDICES

Appendix I: (Planned Study Transition Checklist Between Study Coordinators)

Appendix II: (Planned Study Transition Checklist Between Regulatory Staff)

Authorized by:	Signed Electronically by: Erin Lynch - eelynch@mcw.edu 21-Mar-2025 @ 01:17 PM CDT Reason: Approval CCCTO Administrative Director

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Appendix I: PLANNED STUDY TRANSITION CHECKLIST BETWEEN STUDY COORDINATORS (Pg. 1)

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 (: 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, EPIC Research status names CRC, 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.*

Appendix I: PLANNED STUDY TRANSITION CHECKLIST BETWEEN STUDY COORDINATORS (Pg. 2)

Attestation of Clinical Research Protocol Training

Study Short Title: _____

IRB Number: _____

Principal Investigator: _____

This note serves as documentation that protocol-specific training for the above-referenced clinical research study was conducted on _____(date) for the Newly Appointed Study Staff Member named below.

This training covered all relevant aspects of the study protocol, including but not limited to study objectives, inclusion/exclusion criteria, study procedures, safety monitoring, and reporting requirements.

The Newly Appointed Study Staff Member participated in the training:

This training ensures that all participating study personnel are informed of their responsibilities and capable of conducting the study in compliance with the protocol, Good Clinical Practice (GCP), and applicable regulatory requirements.

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

Appendix II: PLANNED STUDY TRANSITION CHECKLIST BETWEEN REGULATORY STAFF

(A spreadsheet may be created as a more comprehensive way to track the current regulatory activity on studies. Hand offs may be captured via email/electronically.)

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. Study Coordinator, Disease Team Manager, PI & Treating/Enrolling Physicians, Sponsor contacts, update personnel information in OnCore & Florence DOA
- ☐ eBridge updates: Primary regulatory contact updated in eBridge and set up to receive notifications
- ☐ Regulatory Action Items:
  - Pending New Submission? Y / N Status: _____
  - Pending amendments? Y / N Status: _____
  - Pending CPR? Y / N Status: _____
  - Pending reportable events? Y / N Status: _____
- ☐ Communication: All pertinent emails/communications/documentation forwarded to new reg staff member or saved in i: drive?
- ☐ Critical due dates to be aware of? _____

_____	_____	_____
Print (Former Reg. Staff Member)	**Sign**	**Date**
_____	_____	_____
Print (Newly Appointed Reg. Staff Member)	**Sign**	**Date***
_____	_____	_____
Print (Regulatory Manager/Lead)	**Sign**	**Date**

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