MEDICAL COLLEGE OF WISCONSIN CANCER CENTER **Cancer Center Clinical Trials Office**

STANDARD OPERATING PROCEDURE **DOCUMENTING DELEGATION OF AUTHORITY**	
SOP#: 6.2.6.2.3	**Original Approval Date: 7/14/17**
Version#: 3.0	**Current Revision Date: 3/16/20**

1.0 PURPOSE/BACKGROUND

The local Principal Investigator (PI) is responsible for ensuring that only individuals qualified by means of education, training and experience are charged with the authority to perform research-related tasks. FDA regulations require the Principal Investigator (PI) to personally supervise the conduct of research under his/her name. However, delegation of research-related tasks allows other individuals to actively participate in the implementation and conduct of research. While authority to perform specified tasks may be delegated, the responsibility for those tasks always remains with the PI.

2.0 SCOPE

This SOP applies to all studies managed by the MCW Cancer Center Clinical Trials Office (MCW CCCTO).

3.0 RESPONSIBILITY

Study Staff
Principal Investigator (PI)
Sub Investigators
Pharmacy Staff
Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

Master Signature Log (MSL): Log containing all signatures of any person assigned to work on any human research study managed by the MCW CCCTO.

Central Delegation Key: A list of all duties that study staff are authorized to perform based on their role.

Protocol-Specific Delegation of Authority Log (PS-DOA): A typed list of staff designated to work on a specific trial, along with any protocol specific tasks beyond what has been listed on the Central Delegation Key.

Protocol-Specific Tasks: Any tasks not included in the Central Delegation Key, or if a staff member performs a task outside of their role (e.g. CRA obtaining informed consent).

5.0 ROLES AND PROCEDURES

5.1 Delegation of Authority will be documented for all studies managed by the MCW CCCTO. With assistance from the regulatory staff, delegation will be documented using a combination of a Master Signature Log and separate Protocol-Specific Delegation of Authority Log (see appendix 1 & 2). *Sponsor provided delegation logs will not be used.*

5.2 Prior to beginning research-specific tasks, those assigned to play a significant role in research on any trial within the CCCTO will sign the MSL. At time of signature, the study staff member must review the Central Delegation Key (appendix 3).

5.2.1 A significant role is described as one who may perform an activity regulated by the FDA such as informed consent, assessment of the primary endpoints, attribution of adverse events, etc. Nurse Practitioners, Physician Assistants, clinic nurses, apheresis nurses and infusion nurses will not be added to the MSL or PS-DOA log (unless they are delegated to perform activities regulated by the FDA), since they work under the supervision of the Principal Investigator or a Sub-investigator.

5.3 Additional Tasks not captured in the Key are listed as Protocol-Specific Tasks and delegated to appropriate individuals on the Protocol-Specific Delegation of Authority Log. Protocol-specific tasks will also be used if an individual is delegated to perform a task outside the role listed on the Key (i.e. Clinical Research Assistant obtaining informed consent). Specific duties will not be added to the PS-DOA Log if they are already listed in an equivalent form on the Central Delegation Key. Roles not listed in the Key will be listed as Other, and protocol-specific task(s) will be assigned.

5.4 The regulatory staff will add the specific team members to the corresponding PS-DOA log.

5.5 The PI must officially approve any delegates by signing and dating applicable entries of the PS-DOA log. The PS-DOA will be stored in the regulatory file.

5.6 If changes to the study staff or their delegated duties are made, the log will be updated accordingly and signed by the PI. After IRB closure the PS-DOA log will be signed by the PI if staff changes .

5.7 The original MSL will be filed securely in the regulatory office. The PS-DOA log will be housed in the corresponding study regulatory file. Both documents will be scanned into the shared electronic drive.

5.8 The MSL is available to be shared with sponsors, monitors, and auditors in an electronic or photocopied paper format upon request. The original document with wet-ink signatures may be viewed in the regulatory office upon request.

6.0 REFERENCES

Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects. http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) and E6 Good Clinical Practice (GCP)

21 CFR Subpart D §312.53 Selecting Investigators and Monitors

7.0 APPENDICES

Appendix 1: Master Signature Log (MSL) Template

Appendix 2: Protocol Specific Delegation of Authority Log (PS-DOA) Template

Appendix 3: Key - Centralized Delegation of Tasks for Clinical Research

Authorized by: _____
James Thomas, Medical Director

_____
Betty Oleson, CTO Administrative Director

Revision dates:
7/14/17, v 1.0
2/20/18, v 2.0
3/16/20, v3.0

Review dates:
2/20/18, 3/16/20

Key - Centralized Delegation of Tasks for Clinical Research

This document describes the standard research tasks delegated to each role within the MCW Cancer Center Clinical Trials Office. Individuals are delegated the authority to perform the tasks appropriate for their role, as indicated below, unless otherwise noted on a protocol-specific delegation of authority log. Please note: this key may not be all-inclusive; roles not captured here should be listed on the protocol-specific delegation of authority log.

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
GENERAL ACTIVITIES							
Assessment of inclusion/exclusion criteria	Yes	Initial documentation: Requires evidence of confirmation by MD, before subject registration	Initial documentation; Requires evidence of confirmation by MD, before subject registration	No	No	No	No
Informed consent/assent	Yes	Yes, only when approved by the IRB	Yes	No	No	No	No
Vital signs (Height, weight, BP, Pulse, RR, temperature, Pulse ox)	Yes	Yes, under supervision of physician investigator.	Yes, as certified by institution.	No	No	No	No
Assess Performance Status	Yes	Yes	Yes, Research Nurse Only	No	No	No	No
Physical exams	Yes	Yes, under supervision of physician investigator.	No	No	No	No	No
Medical history	Yes	Yes, under supervision of physician investigator.	Clarifications only; Medically focused evaluations done by MD/PA/NP	Yes, medication review only (Pharmacist only)	No	No	No
Orders for test article	Yes	No	No	No	No	No	No

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
Administration of test article	Yes	Yes, under supervision of physician investigator.	No (possible exception made for research nurses in rare cases)	No	No	No	No
Dose Limiting Toxicity determination	Yes	Initial assessment; Requires evidence of confirmation by MD	Initial assessment; Requires evidence of confirmation by MD	No	No	No	No
Maximum Tolerated Dose determination	Yes, in conjunction with overall PI.	Initial assessment; Requires evidence of confirmation by Overall PI	Initial assessment; Requires evidence of confirmation by Overall PI	No	No	No	No
Dose modification (including reductions, holds or restarts)	Yes	Initial assessment; Requires evidence of confirmation by MD	Initial assessment; Requires evidence of confirmation by MD	Initial assessment; Requires evidence of confirmation by MD (Pharmacist only)	No	No	No
ADVERSE EVENTS							
Intake/documentation of symptoms	Yes	Yes, under supervision of physician investigator.	Yes	No	No	No	No
Assessment of grade using CTCAE	Yes	Yes	Initial determination; Requires evidence of confirmation by MD, NP or PA	No	No	No	No
Transcription of grades from CTCAE for abnormal laboratory results	Yes	Yes	Yes	No	Yes	No	No
Assessment of clinical significance of labs	Yes	Yes	Yes, based on if action was taken because of lab value.	No	Yes, based on if action was taken because of lab value.	No	No

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
Assessment of expectedness	Yes	No	Initial determination; Identification based on current version of Investigator Drug Brochure; Requires evidence of confirmation by MD.	No	No	No	No
Assessment of relationship to test article (i.e., attribution/causality)	Yes	Initial determination; Requires evidence of confirmation by MD	Initial determination; Requires evidence of confirmation by MD	No	No	No	No
SAE determination (i.e., event meets criteria for expedited reporting)	Yes	Yes, under supervision of physician investigator.	Yes	No	If pre-specified in protocol; Otherwise requires evidence of confirmation by MD	No	No
Report to sponsor as SAE	Yes	No	Yes	No	No	No	No
DRUG/DEVICE							
Documentation of accountability and adherence by review of subject diary	Yes	Yes	Yes	No	No	No	No
Documentation of accountability and adherence by count of test article returned by subject	Yes	No	No	Yes	No	No	No

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
Drug/device receipt from the sponsor, storage, preparation, dispensation, destruction, unused returns to the sponsor, and related documentation	No	No	No	Yes	No	No	No
SOURCE DOCUMENTS							
Writing in subject's medical record or research chart	Yes	Yes	Yes	Yes	Yes	No	No
STUDY PROCEDURES							
Subject Randomization	Yes	Yes	Yes	No	No	No	No
Lab sample processing, shipping or receiving	Yes	No	Yes	No	Yes	No	Yes
Evaluation of response results	Yes	Initial determination; Requires evidence of confirmation by MD	Initial determination; Requires evidence of confirmation by MD	No	No	No	No
Assessment of primary study endpoints	Yes	Initial determination; Requires evidence of confirmation by MD	Initial determination; Requires evidence of confirmation by MD	No	No	No	No
Physical assessments, cognitive tests (i.e. walk tests, strength tests, measurements, neurocognitive tests, etc.)	Yes	Yes	Yes	No	No	No	No

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
Subject photography	Yes	Yes	Yes	No	No	No	No
Subject Questionnaires, Patient Reported Outcomes	Yes	Yes	Yes	No	No	No	No
IVRS/IWRS access	Yes	No	Yes	Yes, for pharmacy functions	No	No	No
Perform EKGs/ECGs on provided	Yes	Yes	Yes, with documented training.	No	No	No	No
REGULATORY DOCUMENTS							
Maintain regulatory binder or essential documents	Yes	Yes	Yes	Yes, pharmacy specific documents	Yes	Yes	No
CASE REPORT FORMS (CRFs)							
Data transfer from source documents to CRF	Yes	Yes	Yes	Yes, pharmacy specific forms	Yes	No	Yes, study lab specific forms.
Sign completed CRF	Yes	No	No	No	No	No	No
Data query resolution	Yes	No	Yes	Yes, pharmacy specific forms	Yes	No	No
COMMUNICATIONS							
Communications and submissions to sponsors, IRB, or federal authorities, and Froedtert & MCW	Yes	Yes	Yes	Yes	Yes	Yes	No

Research Tasks	Investigator	Physician Assistant (PA) / Nurse Practitioner (NP)	Research Nurse (RN), Clinical Research Coordinator, & Clinical Research Manager	Pharmacist, Pharmacy Assistant/Tech	Clinical Research Assistant	Regulatory Staff	CTO Laboratory Staff
Directly supervise Clinical Research Assistants, Clinical Research Coordinators, & Research Nurses.	No	No	Yes, Clinical Research Manager only.	No	No	No	No

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Protocol-Specific Delegation of Authority Log

For use with central delegation key and Master Signature Log.

PI Name: _____

Sponsor: _____

Protocol Name: _____

Site Name: _____

Individuals are delegated the authority to perform the tasks appropriate for their role, as indicated in the **Key – Centralized Delegation of Tasks for Clinical Research** (Appendix 3 of SOP 6.2.6.2.3). If all tasks are included in the Key, the Protocol-Specific Tasks column will remain blank on the Protocol-Specific Delegation of Authority Log.

The Key may not be all-inclusive. Roles not captured in the Key are listed as Protocol-Specific Tasks below and delegated to appropriate individuals on the Protocol-Specific Delegation of Authority Log. Protocol-specific tasks will also be used if an individual is delegated to perform a task outside the role listed on the Key (i.e. Clinical Research Assistant obtaining informed consent).

☐ **N/A- All tasks follow key. No additional protocol-specific tasks required.**

Protocol-Specific Tasks

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____

I authorize the individuals listed to participate on this protocol and perform the tasks delegated on the central delegation key and as indicated above and these individuals are aware of their additional duties, if indicated.

PI Signature at study initiation: _____ **Date:** _____

PI Signature at study closeout: _____ **Date:** _____

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Protocol-Specific Delegation of Authority Log

For use with central delegation key and Master Signature Log.

PI Name: _____

Sponsor: _____

Protocol Name: _____

Site Name: _____

NAME	ROLE	PROTOCOL-SPECIFIC TASKS	START DATE	ENTERED BY: INITIAL/DATE[1]	START DATE PI INITIAL/DATE	STOP DATE	ENTERED BY: INITIAL/DATE	STOP DATE PI INITIAL/DATE
Ex: John Smith	*Per Key	1,2,3,4,5,6,7,8,9,10	01-JAN-2019	JS 01-JAN-2019	AB 01-JAN-2019	01-JAN-2019	JS 01-JAN-2019	AB 31-DEC-2019

[1] Can be typed at initial document creation.

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Protocol-Specific Delegation of Authority Log

For use with central delegation key and Master Signature Log.

PI Name: _____

Sponsor: _____

Protocol Name: _____

Site Name: _____

NAME	ROLE	PROTOCOL-SPECIFIC TASKS	START DATE	ENTERED BY: INITIAL/DATE[1]	START DATE PI INITIAL/DATE	STOP DATE	ENTERED BY: INITIAL/DATE	STOP DATE PI INITIAL/DATE
Ex: John Smith	*Per Key	1,2,3,4,5,6,7,8,9,10	01-JAN-2019	JS 01-JAN-2019	AB 01-JAN-2019	01-JAN-2019	JS 01-JAN-2019	AB 31-DEC-2019

[1] Can be typed at initial document creation.