MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

# Cancer Center Clinical Trials Office

| STANDARD OPERATING PROCEDURE<br>PROTOCOL IMPLEMENTATION MEETINGS | |
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| **SOP#: 4.4** | **Original Approval Date: 9/13/13** |
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## 1.0 PURPOSE/BACKGROUND

The purpose of this Standard Operating Procedure (SOP) is to describe the process for Protocol Implementation Meetings (PIM) for Phase I and other complex studies managed by the Cancer Center Clinical Trials office (CCCTO). It is critical to have a formal meeting including key personnel involved with a complex clinical trial prior to enrolling the first patient or at any time logistical issues are identified during the conduct of the trial that require staff education or re-education.

## 2.0 SCOPE

This SOP affects all trials that have been identified by a member of the study staff or others as needing an implementation meeting for logistical purposes. This includes all phase I trials, and complex trials as identified by the Research Managers. The PIM assures the compliance and quality of research and that each person understands their role in implementing the clinical trial. This allows the key personnel to ensure everyone involved is trained as applicable, understands the expectations of the protocol, including responsibilities of study staff and what is to be delegated, and to complete a discussion of all logistical aspects of a patient visit. This assures that all protocol–specific issues including, but not limited to, the following areas have been resolved prior to accruing patients: billing, nursing, data collection, laboratory, and pharmacy.

## 3.0 RESPONSIBILITY

The research manager is responsible for initiating the PIM.

The following attendees will be part of the PIM, as applicable:

**Research Staff, as applicable:**
- Study PI and/or Sub-investigator
- Research Managers (RM)
- Disease Team Leads
- Study Coordinators
- Budget and Finance Staff

**Clinical Staff, as applicable:**
- Investigational Drug Pharmacists
- TRU Service Coordinator or designee
- TRU Hem/Onc Tech

- Staff nurse(s)
- Clinical Nurse Specialist
- Inpatient nursing designee
- Cancer Center Lab designee
- Wisconsin Diagnostic Laboratories representative

**Billing Staff, as applicable:**
- OCRICC designee
- Specialty Pharmacy

**Others as assigned**

## 4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

TRU: Translational Research Unit, located in the Cancer Center Day Hospital.

Service Coordinator: The nurse that manages the day-to-day operations of an assigned area of the Cancer Center.

## 5.0 ROLES AND PROCEDURES

5.1 The PIM should preferably be set up at least 1 week before opening the study to patient accrual, but can be set up at any time with Research Manager approval.

5.2 The PIM may be done in conjunction with another protocol specific meeting.

5.3 The following information may be reviewed at the PIM, as necessary, by the meeting attendees:

- Study overview including objectives, design, and purpose
- Study specific tasks to be completed with proposed timeline, feasibility, and logistical requirements
- Investigational product management, storage, ordering, and shipping requirements
- Specific nursing or other staff requirements
- Participant eligibility and registration requirements
- Required source documentation and examples of documentation/informational tools (i.e. flowsheets, tip sheets, etc.)
- Financial pre-determination or pre-certification considerations
- SAE reporting guidelines
- Other processes or procedures that must be defined and implemented prior to enrolling study participants.

5.4 Attendance at the meeting will be recorded and a summary of topics reviewed will be documented. A copy of these documents will be stored in the regulatory file.

## 6.0 REFERENCES

FDA:21 CFR 312.60: Investigator Responsibilities http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60

FDA: 21 CFR 312.62 Investigator Record Keeping and Retention http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

1572 Statement of Investigator http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

## 7.0 APPENDICES

None

Authorized by: _____
James Thomas, Medical Director

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