MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE RECORDING STUDY PARTICIPANT SCREENING AND ENROLLMENT	
SOP#: 5.3	**Original Approval Date: 1/20/14**
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1.0 PURPOSE/BACKGROUND

It is necessary to maintain accurate records of all potential study participants screened for a protocol for many reasons (i.e. to track eligibility issues/patterns, avoid approaching the same patient twice, demonstrate study staff effort, provide evidence that ineligible patients are being excluded, etc.). These logs can provide useful feedback to the sponsor and/or the institution. The purpose of this standard operating procedure (SOP) is to describe the content of the study screening and enrollment logs, the steps for creating and maintaining screening and enrollment logs, and the procedure for providing study sponsors and internal users with reports of screening and enrollment from the OnCore Clinical Trial Management System.

2.0 SCOPE

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

3.0 RESPONSIBILITY

The principal investigator is ultimately responsible to ensure regulatory documents are maintained per FDA, ICH/GCP, regulations and guidelines. The following staff are responsible for entering and maintaining current data in the OnCore clinical trials management system screening and enrollment logs and printing/sending reports of screening and enrollment as required:

- Study Coordinator
- Clinical Research Assistant

4.0 DEFINITIONS

Off Treatment: The participant is no longer treated with protocol prescribed therapy. The participant will continue to be followed per protocol and may undergo protocol defined procedures until the participant is "off study" (see definition below).

Off Study: The participant is no longer being followed per protocol and is no longer undergoing any protocol procedures. The protocol should be consulted to determine the period of time after the participant is "off treatment" before the participant is "off study". If the protocol does not specify a period of time for following the participant, the participant must be followed for any adverse events for at least 30 days after the last protocol treatment or until all study related toxicities have resolved to baseline values or until the start of another treatment. NOTE: some protocols will require participant follow-up indefinitely, on an interval defined in the protocol.

5.0 ROLES AND PROCEDURES

5.1 Enter into OnCore the medical record numbers of potential participants as they are pre-screened for study eligibility, according to the protocol requirements and/or the research team requirements.

5.2 After participant signs an informed consent form, the participant should be registered to the study as a consented subject. . It should also be noted if a participant has limited English proficiency in the comments field. A record of the consent conference must be documented in Epic. (See *6.3.4 SOP Consenting Study Participants*.)

5.3 A copy of the signed informed consent form should be sent to the Office of Clinical Research & Innovative Care Compliance (OCRICC) via email within one business day following the consent date. The copy of the consent sent to OCRICC must have an Epic patient label (preferably from the corresponding Epic encounter if available) affixed to each page, but not obstructing any text.

5.4 After eligibility is confirmed, enter into OnCore verification of eligibility and the name, medical record number, race/ethnicity, and gender of every subject.

5.5 Potential study participants who sign the informed consent form but who are later determined to be ineligible or decline to participate will have the date of consent and reason ineligible and/or reason declined entered into OnCore.

5.6 Additional information entered into OnCore includes the following as relevant to the study: enrollment and randomization status, date On Treatment, date Off Treatment, date On Arm and date Off Arm, Follow-up start date, date of progression, date Off Study and date of death. Any additional explanation that can be provided at each one of those timepoints relevant to IRB reporting should be recorded (i.e. additional details related to off-study or off-treatment reason, cause of death, date of last dose, etc.)
NOTE: Unless the study is an investigator-initiated trial, entering subject information into the On Study page in Oncore, does not constitute enrollment on the trial. Enrollment must be completed in the system identified by the study sponsor.

5.7 Upon sponsor request, staff will provide a copy of the screening log (Protocol Screened Subjects Report) or enrollment log (Protocol Accrual Report) generated from OnCore. Identifiers will be removed prior to sending to the sponsor or uploading to Florence eBinders.

5.8 Study coordinators will not utilize a separate sponsor-provided screening and enrollment log. It is always preferred by the MCW CCCTO to use the OnCore-generated Screening and Enrollment Logs.

6.0 REFERENCES

MCW CCCTO *6.3.4 SOP Consenting Study Subjects*

7.0 APPENDICES

N/A

Authorized by: Signed Electronically by:
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CCCTO Administrative Director

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