

STANDARD OPERATING PROCEDURE PATIENT 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 subjects 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 subjects 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 patient is no longer treated with protocol prescribed therapy. The patient will continue to be followed per protocol and may undergo protocol procedures until the patient is “off study” (see definition below).

Off Study: The patient 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 patient is “off treatment” before the patient is “off study”. If the protocol does not specify a period of time for following the patient, the patient 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 patient follow-up indefinitely, on an interval defined in the protocol.

5.0 ROLES AND PROCEDURES

Cancer Center Clinical Trials Office



- 5.1 Enter into OnCore the medical record numbers of potential subjects as they are pre-screened for study eligibility, according to the protocol requirements and/or the research team requirements. Update the patient Epic Status according to the *OnCore-Epic Crosswalk* (Appendix I).
- 5.2 After subject signs an informed consent form, enter into OnCore verification of eligibility and the name, medical record number, race/ethnicity, and gender of every subject. It should also be noted if a patient has limited English proficiency. A record of the consent conference must be documented in Epic. (See *6.3.4 SOP Consenting Study Subjects*.) Update the patient Epic Status according to the *OnCore-Epic Crosswalk* (Appendix I).
- 5.3 A copy of the patient's 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 Potential study subjects who sign the informed consent form but who are later determined to be ineligible or refuse to participate will have the date of consent and reason ineligible and/or reason refused entered into OnCore. Update the patient Epic Status according to the *OnCore-Epic Crosswalk* (Appendix I)
- 5.5 At the time the subject is successfully enrolled in clinical trial, an FYI flag should be added to the patient's chart in Epic, indicating that the patient is a research participant. The Z00.6 code must be added to the patient's problem list. Update the patient Epic Status according to the *OnCore-Epic Crosswalk* (Appendix I)
- 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.)
- 5.7 Upon sponsor request, staff will provide a copy of the screening log (Protocol Screened Subjects Report) or enrollment log (Protocol Accrual Report) printed from OnCore. Identifiers will be removed prior to sending to the sponsor.
- 5.8 Study coordinators will not utilize a separate sponsor-provided screening and enrollment log unless approved by the research manager overseeing the study. It is always preferred by the MCW CCCTO to use the OnCore-generated Screening and Enrollment Log.

6.0 REFERENCES

MCW CCCTO *6.3.4 SOP Consenting Study Subjects*

7.0 APPENDICES

Appendix I: Epic OnCore Crosswalk

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Revision dates:

- 1/20/14, v 1.0
- 3/2/15, v 2.0
- 1/8/16, v. 3.0
- 2/14/17, v. 4.0
- 3/16/20, v. 5.0

Review dates:

- 3/7/14, 3/2/15, 1/8/16, 2/14/17, 2/20/18, 3/16/2020

Appendix I: OnCore-Epic Crosswalk

OnCore Status/Step	Epic Research Status	Description
Entered to Pre-Screening Log	Identified	Patient is in consideration for a study.
	Pre-Screening Interest Identified (Watson) [not used by study staff]	Patient has had a preferred trial selected via the Ask Watson feature.
Consented	Consented	Patient has consented to the trial.
Ineligible (+ reason)	Declined	Patient declined the trial (prior to consent)
	Ineligible	Patient does not meet eligibility criteria (pre or post consent).
	Pre Screening Interest Withdrawn (Watson)	Provider has removed the preferred status of the trial.
On-Study, On Treatment	Enrolled	Patient has been placed on study and/or receiving treatment on the trial.
Follow- Up	Off Active Treatment, in Follow Up	Patient is off treatment on a trial and will be followed for survival per protocol. Bill component present.
	Long-Term Follow-Up [used by OCRICC only]	OCRICC will use this status to designate that a patient no longer requires following for billing purposes on the trial.
Off-Study	Completed	Patient has completed the protocol-defined follow-up period. This status also includes patients who are deceased.
Off-Study (Withdrawn)	Withdrawn	Patient consented to the study and may have been enrolled, but has since withdrawn interest from participation and declines follow-up.