MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE DOCUMENTING INFORMED CONSENT FOR STUDY SUBJECTS	
SOP#: 6.3.4	**Original Approval Date: 11/7/14**
Version#: 5.0	**Current revision Date: 3/13/25**

1.0 PURPOSE/BACKGROUND

The purpose of this Standard Operating Procedure (SOP) is to describe the process where a patient is presented with the option of research study participation, the process of obtaining informed consent, and the disposition of the consent form(s) after it is signed. This also describes the continuing process of informed consent in research.

2.0 SCOPE

This SOP applies to all studies that utilize an informed consent form for research managed by the MCW Cancer Center Clinical Trials Office.

3.0 RESPONSIBILITY

Study staff
Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

5.0 ROLES AND PROCEDURES

5.1 **Process for Obtaining Informed Consent of a Potential Study Subject:**

5.1.1 A study staff member will review the consent form with the potential study subject (or Legally Authorized Representative, if necessary).

5.1.2 Potential subjects will be given adequate time to review the consent form and all questions will be answered.

5.1.3 Required signatures will be obtained by a member of the study staff. A witness should only sign when required per MCW IRB policy. If a witness signs the document when not required, the study staff should document in the medical record (or note to file) the relationship to the patient and why a witness signed. (I.e., "Although not required, the subject's spouse was present during the consenting process and signed as a witness." Or "Although not required, hospital staff was present for consenting process and signed as a witness.")

5.1.4 The consent process will be documented in the patient's medical record, in accordance with FDA regulations and GCP guidelines.

5.1.5 Study subjects will be provided with a copy of the signed and dated consent form.

5.2 **The Continuing Process of Informed Consent:**

5.2.1 During study visits, research staff will assess participant understanding and willingness to continue, documenting these conversations in the electronic medical record. The study staff will periodically assess the participant's capacity to consent. Any changes in their decisional abilities will be documented by the treating physician.

5.2.2 Any new risks, benefits, or changes to the protocol will be communicated to the participants. If changes impact participation, a revised consent form must be reviewed and signed. Subjects that require reconsenting will be defined in the IRB amendment submission. All revisions will be reviewed with the applicable study subjects at the next appropriate opportunity.

5.2.3 Study subjects will not be reconsented for continuing reviews.

5.2.4 Subjects will not be reconsented for the sole purpose of a change in PI as this is unlikely to impact their decision to continue study participation. However, study staff will notify subjects of this change with updated contact information in an IRB-approved letter.

5.2.5 The process for obtaining informed consent will again be performed as outlined in section 5.1.

5.3 **Disposition of the Signed Consent Document:**

5.3.1 The signed and dated copy of the consent form will be sent to all appropriate business partners, as needed (e.g., OCRICC, Wisconsin Diagnostic Laboratories, sponsor, etc.).

5.3.2 A scanned copy of the informed consent will be available in the Media tab in the electronic medical record.

5.3.3 All original signed and dated consent forms (including screen fails) will be stored with the study subject records.

5.4 **Consenting Study Subjects Who Demonstrate Limited English Proficiency, Limited Literacy, or Limited Decisional Abilities:**

5.4.1 The MCW CCCTO will follow the MCW IRB policy for these subjects.

6.0 REFERENCES

MCW IRB SOP: *Informed Consent and Documentation for Human Subject Research*

MCW IRB SOP: *Legally Authorized Representatives (LAR's): Who Can Consent on Behalf of an Adult Subject With Decreased Decisional Ability?*

MCW IRB SOP: *Recruitment and Enrollment of Non-English Or Limited English-Proficient Subjects*

45 CFR 46.116 *General Requirements for Informed Consent*

45 CFR 46.117 *Documentation of Informed Consent*

7.0 APPENDICES

None

Authorized by:	Signed Electronically by: Erin Lynch - eelynch@mcw.edu 21-Mar-2025 @ 01:16 PM CDT Reason: Approval CCCTO Administrative Director

Revision dates:
11/7/14, v 1.0
2/14/17, v 2.0
2/20/18, v 3.0
11/5/21, v 4.0
3/13/25, v 5.0

Review dates:
3/2/15, 1/8/16, 2/14/17, 2/20/18, 3/16/20, 11/5/21, 3/13/25