MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE CONSENTING STUDY SUBJECTS	
SOP#: 6.3.4	**Original Approval Date: 11/7/14**
Version#: 3.0	**Current revision Date: 2/20/18**

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 providing informed consent, and the disposition of the consent form(s) after it is signed. This also describes the continuing process of the 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 (and Legally Authorized Representative, if necessary).

5.1.2 Potential subjects will be given adequate time to review the consent form and all subject's 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 FH/MCW IRB policy. If a witness signs the document when not required, the study staff should document in the legal 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 the 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 legal 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 Subjects that require reconsenting will be defined in the IRB approved amendment submission. All revisions will be reviewed with the applicable study subjects at the next appropriate opportunity. Study subjects will not be reconsented for continuing reviews.

5.2.2 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 (i.e. OCRICC, Wisconsin Diagnostic Laboratories, etc.)

5.3.2 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/FH IRB's policy for these subjects.

6.0 REFERENCES

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

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

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

MCW/FH IRB SOP: *Legally Authorized Representatives (LARs): Who Can Consent on Behalf of an Adult Subject with Decreased Decisional Ability?*

45 CFR 46.116 *General Requirements for Informed Consent*

45 CFR 46.117 *Documentation of Informed Consent*

7.0 APPENDICES

None

Authorized by: _____ _____

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