MEDICAL COLLEGE OF WISCONSIN CANCER CENTER **Cancer Center Clinical Trials Office**

STANDARD OPERATING PROCEDURE **COMPLETING THE FDA 1572, FINANCIAL DISCLOSURES, & CVS**	
SOP#: 6.2.6.2.1	**Original Approval Date: 5/8/13**
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1.0 PURPOSE/BACKGROUND

The purpose of this Standard Operating Procedure (SOP) is to describe the process for completing the Food & Drug Administration's Form FDA 1572 ("1572"), Statement of Investigator, as well as financial disclosure information, and curriculum vitae (CV).

2.0 SCOPE

This SOP affects all studies that require a 1572 and financial disclosure information to be completed for study conduct. This SOP identifies the steps for fulfilling this regulatory requirement.

3.0 RESPONSIBILITY

Principal Investigator (PI)
Sub-investigators
Regulatory Staff
Study Staff
Other support staff as needed

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

Form FDA 1572: The Statement of Investigator; an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

Curriculum Vitae (CV): a written overview of a person's experience and other qualifications

5.0 ROLES AND PROCEDURES

5.1 The 1572 will be completed by the regulatory staff on behalf of the PI prior to any FDA regulated study opening through the Cancer Center Clinical Trials Office (CCCTO).

5.2 The Principal Investigator will be listed in section 1 of the 1572.

5.3 Only individuals who make a direct and significant contribution to the clinical data, specifically physician sub-investigators, will be listed in section 6 of the 1572. The MCW CCCTO considers only physician sub-investigators to be qualified as appropriate experts to investigate the drug(s) involved in the studies conducted through the CCCTO. Other

individuals working under the direction of the PI or sub-investigator will not be listed in section 6 of the 1572 (e.g., Nurse Practitioners; Physician Assistants; nurses; study coordinators; OR residents, fellows, or students in clinic rotation), as they rarely meet these criteria.

5.4 The 1572 only requires updating when additional sub-investigators are added to section 6 of the form or the PI changes in section 1. Other changes (e.g., IRB address change, addition of a clinical research lab, removal of sub-investigators) will be documented in the study records and will be reflected at the next required 1572 update. Note: The 1572 may be updated more often than required at the discretion of the regulatory staff.

5.5 Individuals listed on the 1572 will complete financial disclosure forms as required by the sponsor and MCW policy, in addition to any other study staff members with significant financial interest.

5.6 The PI will review, sign, and date the 1572 upon completion.

5.7 The MCW Principal Investigator and sub-investigator(s) will provide a CV to demonstrate their qualifications by education, training, and experience. Each CV will contain the investigator's current faculty appointment at Medical College of Wisconsin. CVs and medical licenses will be kept on file for only those that are listed as investigators on the 1572. CVs generated by electronic systems or sponsor databases (e.g., Shared Investigator Platform) will be considered to be an acceptable substitute for a MCW CV for clinical research purposes provided all necessary information is included.

5.8 In accordance with the local regulatory authority (FDA) and the international standard (ICH GCP), MCW CCCTO CVs do not expire and are not required to be signed and dated. CVs will not be modified or abbreviated on a per study basis, as all investigator qualifications are accurately captured in the full version of each CV. Ad hoc updates to CVs may be made at the investigator or sub-investigator's discretion. Otherwise, the CV provided during study start-up will be considered accurate, up-to-date, and current without expiration.

5.9 No information on any CV will be redacted by MCW CCCTO staff. If a study sponsor requires redactions, the study sponsor may redact the information in accordance with the sponsor requirements.

6.0 REFERENCES

1.) Form FDA 1572
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

2.) *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* U.S. Department of Health and Human Services, Food and Drug Administration, Office of Good Clinical Practice, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), May 2010

7.0 APPENDICES

None

Authorized by: _____ _____

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