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.

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.

5.0 **ROLES AND PROCEDURES**
5.1 The 1572 will be completed by the PI (with assistance from the regulatory staff and/or other support staff as needed) prior to the study opening through the CCCTO.
5.2 The Principal Investigator will be listed in section I of the 1572.
5.3 Only individuals that 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 (i.e. Nurse Practitioners, Physician Assistants, nurses, study...
coordinators, residents/fellows/students in clinic rotation), as they do not 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 (i.e. IRB address change, addition of a clinical research lab, removal of sub-investigators, etc.) 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 Those listed on the 1572 will complete financial disclosure forms as required by the sponsor, in addition to any other study staff members with significant financial interest.

6.0 REFERENCES

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


7.0 APPENDICES
None

Authorized by: James Thomas, Medical Director Betty Oleson, CTO Administrative Director

Revision dates: 5/8/13, v 1.0

Review dates: 3/7/14