MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE SOP ON SOPS	
SOP#: 1.1	**Original Approval Date: 2/28/13**
Version#: 5.0	**Current Revision Date: 11/5/2021**

1.0 PURPOSE/BACKGROUND

A Standard Operating Procedure (SOP) is a set of written instructions that documents policies and procedures, sufficiently detailed to cover routine operations required in conducting clinical investigations. The Cancer Center Clinical Trials Office (CCCTO) SOPs document the way clinical research activities are performed to facilitate consistency and to support quality clinical research. The SOPs are intended to assist in ensuring compliance with the Medical College of Wisconsin, state, and federal regulations, guidelines, policies, and procedures.

2.0 SCOPE

SOPs help assure the compliance and quality of research and that each person in the process carries out his or her duties. In addition, SOPs should contain enough detail to be useful in guiding an individual through a particular procedure and thereby establish uniformity in the everyday functions of the departments. In addition, this SOP will establish a uniform procedure for creating and maintaining SOPs for the CCCTO.

3.0 RESPONSIBILITY

Individuals with appropriate knowledge of the subject matter and the internal structure of the CCCTO may write or provide feedback on SOPs, which may include:

- Research Managers
- Team Leads
- Study Coordinators
- Clinical Research Assistants
- Administrative staff
- Regulatory staff
- Budget and Finance staff
- Education staff
- Quality Assurance staff
- Program Managers
- Physician Investigators
- Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions

5.0 ROLES AND PROCEDURES

5.1 SOP Format

SOPs will be written in the same standardized format to allow for continuity. This SOP will serve as the template. This template should always be used when starting a new SOP. Writer should be sure to use "Save As" command as to not overwrite the SOP template.

- SOPs should have a header with the MCW logo left justified followed by "Cancer Center Clinical Trials Office" (Georgia, 14 point font, bold).
- Immediately under the header, on the first page only, a table will contain the following information: Title "Standard Operating Procedure" followed by the Title on the second line, identifying the subject of the SOP. Included in the table should be SOP#, Version#, Original Approval Date, Revision Date and the date that this revision replaces.
- SOPs should have a footer on each page of the SOP. On the first line the SOP Title/Number should be listed (Georgia, 11 point font, non-bold). The second line should contain the page number, listed as: Page # of #.
- SOP body should be written in Georgia, 11 point font, non-bold.
- SOPs should have an "Authorized by" section that will be electronically signed by the Administrative Director of the CCCTO once approved.

5.2 Body of SOP

The following section headings are required in each SOP:

1.0 Purpose/Background
2.0 Scope
3.0 Responsibility
4.0 Definitions
5.0 Roles and Procedures
6.0 References
7.0 Appendices
Revision dates

5.3 Writing SOPs

All recognized CCCTO sub-committee member, research managers, and team leads have the authority to create any SOPs they feel are necessary that pertain to their agendas, and/or have the right to delegate this authority to other members of the CCCTO. The Medical Director and Administrative Director of the CTO have the authority to create, delegate, authorize and distribute SOPs independent of the guidelines of this SOP. Each committee will follow their established guidelines for the actual writing of the SOPs. Draft SOPs should be saved to the Draft SOPs folder in the I: Drive.

SOP# will be assigned by designated CTO staff.

5.4 **Review and Approval of SOPs**

After an SOP is written the proposed draft SOP will be presented to the CTO Administrative Director for an initial review. After the CTO Administrative Director's initial approval, the draft SOP will be uploaded to a website for comments for at least 14 days prior to the proposed approval date, but for no more than 30 days. It will be watermarked to indicate it is a draft. Contact information will be provided for SOP corrections and suggestions. The draft SOP will be shared with all applicable staff and business partners (OCRICC, IRB, Wisconsin Diagnostic Laboratories, MCP, etc.) through an email distribution list of applicable individuals.

Suggestions for revisions will be reviewed and incorporated as appropriate. After the appropriate changes are made, the finalized draft will be presented to the Administrative Director for review, approval and signature. The CCCTO Medical Director may review and approve SOPs for distribution in the absence of the Administrative Director.

- **SOP Number:** is the number corresponding to the outline of SOPs in the table of contents.
- **Original Approval Date:** is the date the Medical Director and Administrative Director sign the original SOP. This date will not change.
- **Current Revision Date:** is the date of the updated SOP and which previous version date it replaces. All SOP version dates will be listed at the bottom of the SOP, chronologically with the most recent on the bottom of the list.
- **Version #:** once an original SOP has been approved the number will start at 1.0. Each updated SOP (with a new revision date) should be given a new number after approval – 2.0, 3.0, etc.

5.5 **Distribution**

Once the signatures are obtained, all version of the SOP will be made available on the CCCTO Approved SOPs folder in the shared I: Drive and in the Florence eBinders system. The current versions will be available on the Clinical Trials Office website (public). An email will be sent to a distribution list of all applicable staff and business partners (OCRICC, IRB, Dynacare, MCP, etc.) impacted by the SOP notifying them of the new/updated SOP. The notification will also include information about how long the proposed SOP will be posted as a draft. It is the responsibility of all recipients of the new SOP to review the newly distributed SOP. The newly distributed SOP will go into effect on the date in which is signed off by the CCCTO Administrative Director.

5.6 **Revisions**

A new or revised SOP must be generated any time there are needed changes in procedures/policies. Possible need for revision will be monitored by the originating sub-committees and members of the CCCTO. Review, approval, and distribution of revisions will follow the same process as new SOPs described above. Revisions involving only minor

administrative or minor process changes may not be posted to website for review prior to posting as final, at the discretion of the SOP sub-committee.

5.7 **Reviews**

Existing SOPs will be reviewed by the SOP sub-committee at a minimum of every two years for applicability and/or possible revisions. Scheduled reviews will be conducted during the first quarter of the corresponding calendar year.

5.8 **SOP Compliance**

Compliance with SOPs is required of all CCCTO staff and will be monitored throughout the year. This compliance will be incorporated into reviews and performance enhancement plans. Documentation is available for review by applicable individuals, regulatory agencies and administration. Deviations from SOPs must be documented by the staff member discovering or planning the deviation. Deviations may require re-education of SOP by Research Manager and/or Education Quality Assurance Staff, which also must be documented. Printing of SOPs is discouraged. SOPS should be accessed via Florence eBinders or the Cancer Center CTO website (https://www.mcw.edu/departments/cancer-center/clinical-trials/sops-for-research-staff).

6.0 REFERENCES

Federal, State, and Medical College of Wisconsin regulations/policies are the governing SOPs and the MCW CCCTO SOPs are not in conflict with those policies/regulations.

7.0 APPENDICES

None.

Authorized by:

Signed Electronically by:
Betty Oleson - boleson@mcw.edu
11-Feb-2022 @ 08:53 AM CST Reason: Approval

CCCTO Administrative Director

Revision dates:
2/28/13, v 1.0
3/2/15, v 2.0
2/14/17, v 3.0
2/20/18, v4.0
11/5/2021, v5.0

Review dates:
3/7/14, 3/2/15, 1/8/16, 2/14/17, 2/20/18, 3/16/20, 11/5/21

Current Electronic Signatures (v.6):

Signed electronically by: Betty Oleson (boleson@mcw.edu)

Date: *11-Feb-2022 @ 08:53 AM CST*

Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.