***Development, Implementation, and Maintenance of Standard Operating Procedures (SOPs)***

1. **PURPOSE**

The purpose of this document is to establish a uniform process for the preparation, review, implementation, and retirement of a Standard Operating Procedure (SOP). **(MANDATORY LANGUAGE)**

1. **SCOPE**

This Standard Operating Procedure applies to the development and maintenance of all clinical trial SOPs, and related appendices. The following procedures apply to all SOPs and associated documents, developed or revised, after this SOP’s effective date. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details necessary to further define the scope of this SOP]*

1. **POLICY**

In the management of clinical trials it is critical to define and adhere to uniform process standards that are consistent with institutional, state, federal, and international policies, and regulatory requirements. The standards to achieve uniform processes are established and defined within Standard Operating Procedures and any associated appendices, and/or templates. **(MANDATORY LANGUAGE)**

**Additional Regulations or Policies ☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

APPENDIX: Supplemental document providing information to support the requirements of a Standard Operating Procedure

APPROVAL DATE: The date on which the SOP is approved for use

DEVIATION: Formally documented, unplanned departure from an SOP

EFFECTIVE DATE: The date on which a new or revised SOP is first implemented

STAKEHOLDER: An individual or group who is involved in or affected by a course of action

STANDARD OPERATING PROCEDURE (SOP): An established or prescribed method to be followed routinely for the performance of designated operations or in designated situations

SUBJECT MATTER EXPERT (SME): The individual(s) who exhibit the highest level of expertise in performing a specialized job, task, or skill within an organization

WAIVER: A planned, pre-approved departure from a standard procedure or practice

WORK INSTRUCTION (WIN): A supporting document containing detailed instructions for performing a task; a Best Practice

“Many of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 26-Mar-2015 and are subject to change. Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance.”

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

All members of the organization are responsible for regularly reviewing those SOPS relevant to their job title and for completing any related, required training. In addition, any individual affected by the SOP may bring forward recommendations for the addition, revision or retirement of an SOP. **(MANDATORY LANGUAGE)**

**SOP Administrator(s)/Designee**

An individual filling the SOP Administrator role is *accountable* for the creation, implementation and management of Standard Operating Procedures. The Administrator or Designee shall be responsible for the following activities: **(MANDATORY LANGUAGE)**

* Ensures all routine operations and activities are documented by SOPs
* Initiates and/or approves proposals for SOP creation, revision and/or retirement
* Approves SOPs and associated documents
* Reviews SOP waivers and deviations
* Identifies roles/ job titles within the organization for which an SOP is applicable
* Ensures employees regularly review relevant SOPs and receive training as needed
* Documents and tracks SOP revisions and approvals

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the SOP Administrator(s)/Designee]*

**SOP Author**

An individual filling the SOP Author role is responsible for the creation or modification of a Standard Operating Procedure. The Author shall be responsible for the following activities:

* Submits request to the SOP Administrator/Designee to create, modify or retire an SOP
* Develops or revises the SOP content
* Aligns the SOP with applicable University policies and regulatory requirements
* Gathers feedback from SOP users and other key stakeholders
* Revises the SOP draft to incorporate feedback as needed
* Completes quality control of the SOP (e.g., formatting and consistency of terms)
* Obtains approval from the SOP Administrator or Designee

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the SOP Author]*

**Additional Roles and Responsibilities**  **☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

**SOP Development or Revision**

When there is a need to create a new SOP or modify an existing one, obtain prior approval from the SOP Administrator or Designee. Once approved for development or revision, the SOP Author collaborates with Subject Matter Experts to develop appropriate content.

**(MANDATORY LANGUAGE)**

**General Considerations for Writing Standard Operating Procedures:**
When writing or editing an SOP, use clear, concise language. The SOP should provide enough detail to ensure it is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work. Additional details such as step-by-step instructions should be outlined in separate work instructions or other supporting documents.**(MANDATORY LANGUAGE)**

SOPS should describe the task to be performed, how it will be carried out, and by whom, using job title, role, or functional area to identify responsible parties. Standard Operating Procedures should include recommended supporting documentation such as approval forms or tracking logs, which serve as evidence that the SOP has been carried out.

**(MANDATORY LANGUAGE)**

**SOP Review, Approval, and Implementation**

The SOP Author obtains input from SOP reviewers and any other key stakeholders. Feedback is incorporated as agreed upon by the SOP team. The draft SOP is checked for alignment with existing policies and standards such as format, version control, etc. The final version and related appendices are submitted to the SOP Administrator or Designee for review and approval.**(MANDATORY LANGUAGE)**

Once the SOP has been approved, the SOP is released for use. The SOP Administrator identifies the affected individuals and ensures they are formally notified of the SOP change. The SOP Administrator or Designee ensures that all affected individuals have received any related training on the use of the SOP prior to implementation. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the process for SOP review, approval and implementation]*

**SOP Retirement**

An SOP may be retired when it is no longer relevant to the work being performed or has been superseded by a related or new SOP. To retire an SOP, approval is obtained from the SOP Administrator or Designee. If approved, the retired SOP should be stored in an area designated for inactive SOPs. The SOP Administrator or Designee ensures that affected individuals are formally notified when an SOP has been retired and that any SOP intended to replace it is identified. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the process for retiring an SOP]*

**SOP Deviations**

SOP deviations are documented and reviewed by the SOP Administrator or Designee. Documentation related to the deviation is retained per record retention policies. The frequency and nature of deviations should be routinely evaluated by the SOP Administrator or Designee. Frequent or significant deviations from an established SOP may indicate the need to revise the SOP, provide additional training, or take other action to reduce the number or the significance of deviations reported. Deviations are reported to the appropriate clinical trial oversight groups (regulatory, funding agencies, etc.) where required. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the process for documenting and tracking SOP Deviations]*

**SOP Waivers**

SOP Waivers are utilized for exceptional circumstances and require advance approval from the SOP Administrator or Designee. Documented approval of the waiver will be stored and retained according to relevant record storage and retention policies. Waivers are reported to the appropriate clinical trial oversight groups (regulatory, funding agencies, etc.) where required. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the process for documenting and tracking* SOP Waivers]

**SOP Review Schedule**

All SOPs should be reviewed on a periodic basis to ensure the content remains relevant, accurate and continues to meet federal, institutional and departmental guidelines. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the SOP review schedule]*

**SOP Tracking and Storage**

The location of current, approved SOPs and relevant supporting information should be documented to ensure the SOPs are readily available. Retired SOPS, Waivers, and Deviations are also stored for reference purposes in accordance with relevant record storage and retention policies. **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding SOP tracking and storage]*

**Additional Procedures** **☐ N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

University of Michigan Standard Practice Guides

<http://spg.umich.edu/>

University of Michigan Health System Policies

<http://www.med.umich.edu/i/policies/umh/toc.html>

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

**Appendix A:** SOP Format Template  ☐ N/A

**Appendix B:** SOP Deviations and Waivers Form ☐ N/A

**Appendix C:** Appendix Header Template ☐ N/A

**Appendix D:** SOP Training Log ☐ N/A

**Appendix E:** SOP Version History Log  ☐ N/A

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP appendices]*