MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

STANDARD OPERATING PROCEDURE PROCESS CHANGE MANAGEMENT	
SOP#: 1.2	**Original Approval Date: 3/25/13**
Version#: 3.0	**Revision Dates: 3/19/2025**

1.0 PURPOSE/BACKGROUND

This SOP is meant to control changes that impact the clinical trials process in the Cancer Center Clinical Trials Office (CCCTO). This SOP seeks to provide a method to introduce change into the clinical trials process which allows the CCCTO staff to provide feedback and properly prepare for the changes. This SOP also provides a method to manage changes which are introduced as emergency changes and provide senior leadership a method to approve changes that result in the suspension of clinical trials when needed.

2.0 SCOPE

This SOP describes the process for managing changes to the clinical trials process in the CCCTO.

3.0 RESPONSIBILITY

Individuals impacted by the process changes in the CTO, which may include:

- CTO Staff
- Administrative staff
- Budget and finance staff
- Investigators
- Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Additional definitions:

Process Change: Any modification to existing workflows, procedures, or systems that impact the conduct of clinical trials.

Change Requestor: The individual or department initiating a process change request.

Impact Assessment: A structured evaluation of the potential effects of a proposed change on operations, compliance, and stakeholders.

Appropriate Leadership: MCW leadership and leadership from the department or organization requesting the process change that are able to make necessary decisions.

Change Initiator	MCW Leadership	Change Initiator Leadership
Froedtert Hospital (FH)	Joint Research Committee	Joint Research Committee
Wisconsin Diagnostic Laboratories (WDL)	Wisconsin Diagnostic Laboratories Medical Director	Chief Operating Officer
IRB & Ancillary Committees	Sr. Assoc. Dean Research	Head of Committee
Medical College Physicians (MCP)/Clinical Practice Service (CPS)	Sr. Assoc. Dean Research	Executive Director of CPS
Cancer Center Clinical Trials Office		Cancer Center Associate Director for Clinical Research or the Cancer Center CTO Medical or Administrative Director

5.0 ROLES AND PROCEDURES

5.1 Initiation of Process Change

1. When the CCCTO is notified of a significant change that will impact operations within the CCCTO, the Change Requestor will be asked to provide the following information to appropriate leadership:
    - Description of the proposed change
    - Rationale for the change
    - Potential impact on workflows, compliance, and stakeholders
    - Risk assessment and mitigation plan
    - Proposed timeline for implementation

5.2 Review and Approval

1. Appropriate CCCTO leadership will review the provided information and conduct an Impact Assessment, involving other CCCTO staff and others as appropriate.
2. The CCCTO may request additional information or modifications before a decision is made.
3. The CCCTO will make determine if the change can be implemented as requested or if additional information or other changes are needed prior.

5.3 Implementation

1. If approved, the Change Requestor will collaborate with relevant teams to develop an implementation plan.

2. The CTO Education team will ensure appropriate staff are educated on new procedures before the go-live date.
3. Any updates to SOPs, templates, guidelines, or electronic systems will be documented.

5.4 Monitoring and Evaluation

1. The CCCTO Leadership (or a designee) will monitor the initial implementation phase and collect feedback from stakeholders.
2. Any unintended consequences or concerns will be addressed as appropriate.

5.5 Documentation and Recordkeeping

1. All change requests, approvals, and implementation records will be stored in the CCCTO shared drive.
2. Training records will be maintained for compliance verification.

1.0 REFERENCES

None

2.0 APPENDICES

N/A

Authorized by:	Signed Electronically by: Erin Lynch - eelynch@mcw.edu 21-Mar-2025 @ 12:54 PM CDT Reason: Approval CCCTO Administrative Director

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