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#: 2.0	**Revision Dates: 2/11/2022**

1.0 PURPOSE/BACKGROUND

This SOP is meant to control changes that impact the Clinical Trials Process in the Cancer Center Clinical Trials Office (CC CTO). In the past changes have been introduced which have effectively suspended some clinical trials without the approval or knowledge of senior leadership. This SOP seeks to provide a method to introduce change into the Clinical Trials Process which allows the CC CTO 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 which suspend clinical trials when needed.

2.0 SCOPE

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

3.0 RESPONSIBILITY

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

- Clinical Research Managers – (RM) – Disease Team Leads
- Clinical Research Nurses
- Clinical Research Coordinators
- Clinical Research Assistants
- Administrative staff
- Regulatory staff
- Budget and Finance staff
- Program Managers
- Clinical Research Management System (OnCore) staff
- Principal Investigators
- Education/Quality Assurance Staff
- Others as assigned

4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Additional definitions:

Change Initiator: Any party introducing changes to the CTO Clinical Trials Process

Normal Change: Change initiated with a feedback time period and a target implementation date; typically 30 - 60 days.

Emergency Change: A change introduced for immediate implementation.

Suspension of Research: For actively accruing studies suspension of research occurs when any change prevents subjects from enrolling in the study or will delay the subjects from enrolling. For studies which are waiting for approval suspension of research occurs when changes cause or will cause studies from being approved more than 5 additional business days.

Appropriate Leadership: MCW leadership and leadership from the organization initiating the change that is at an appropriate level to make institutional research decisions including the suspension of research activities.

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 Director

Organizations' websites (for posting change requests) – Website that have a dedicated area for posting changes with their planned effective date.

- IRB - http://www.mcw.edu/hrpp.htm

Studies Impacted by Change – An identification as to which research studies are impacted by changes being introduced to be defined as one of the following:

- ONLY NEW STUDIES AFTER IMPLEMENTATION DATE

  All new studies going forward; will not apply to any study first approved BEFORE implementation date

- ALL STUDIES, BUT ONLY DURING REVIEW CYCLES

  All new studies going forward; and will be applied to older studies as they come up for Continuing Review or Amendment

- IMMEDIATELY EFFECTIVE FOR ALL STUDIES

All new studies going forward AND all older studies effective on the date of implementation (i.e., applies to all studies immediately)

5.0 ROLES AND PROCEDURES

IDENTIFY CHANGES BEING INTRODUCED TO THE CTO PROCESS – ALL STAFF

5.1 Any CC CTO staff member who becomes aware of changes being introduced to CC CTO processes will bring them to the attention of the Education / Quality Assurance staff.

5.2 CC CTO staff will not change CTO processes until approved following this SOP.

5.3 Education / Quality Assurance staff will track all changes being introduced to the CTO processes until the change is implemented or withdrawn.

EVALUATE AND CATEGORIZE PROCESS CHANGES – EDUCATION / QUALITY ASSURANCE STAFF

5.4 Education/Quality Assurance staff will evaluate the change being requested to determine if it will impact the timeline of existing or new studies.

5.4.1 If an organization has a dedicated website for posting proposed changes 30 – 60 days prior to implementation it is the responsibility of the Education / Quality Assurance staff to monitor that site. These postings will be treated as Normal Change requests.

5.5 The Education/Quality Assurance staff will contact the initiator of the change and clarify exactly what changes are being requested including the Studies Impacted by Change.

5.6 The Education/Quality Assurance staff will determine the Subject Matter Experts (SMEs) most familiar with processes that would be impacted by the change and request they analyze the change.

5.7 The process SMEs will determine the impact of the change being requested.

5.8 The process SMEs will provide a recommendation on how the impact on the research process can be minimized if appropriate.

5.9 If modifications to the change have been made, the Education/Quality Assurance staff will work with the initiator of the change to see if the recommendations can be incorporated.

5.10 If the evaluation shows that the change will not impact the timelines of studies and implementation of the change can be done with minimal effort the change will be processed as an insignificant change.

5.11 If the evaluation shows that the change will impact study timelines or that implementation of the change will require significant effort then the change will be processed as a significant change.

5.12 If a change has been initiated for immediate implementation, the change will be brought to the attention of the CTO Administrative Director to be processed as an emergency change request.

5.13 If a significant change has been presented as a request for change it will be processed as a Normal Change Request.

5.14 The Education/Quality Assurance staff will bring all significant changes to the attention of the CTO Administrative Director for approval.

CHANGE APPROVAL PROCESS – CTO ADMINISTRATIVE DIRECTOR (CTO AD)

5.15 The CTO AD will evaluate all changes being initiated to the CTO processes.

5.16 If the change has been initiated as a normal change request and they determine that the impact to research processes is acceptable the CTO AD will approve the change for implementation.

5.17 If the change has been initiated as an emergency or the impact to the CTO processes is unacceptable the CTO AD will escalate requested change to the Appropriate Leadership for approval. The CTO AD will indicate if the change is presented as an emergency change and / or if the change seems to have an unacceptable impact to the research process. The CTO AD will ask the Appropriate Leadership to take one of 3 actions:

5.17.1 Approve the change to be implemented as a Normal Change to be planned and implemented accepting the impact to the research processes when implemented.

5.17.2 Approve the change for immediate implementation (ASAP) accepting the **suspension of research** studies being impacted by the change until the change is implemented.

5.17.3 Reject the change requested.

5.18 The CTO AD will communicate the decision of the Appropriate Leadership to the Change Initiator and the Education/Quality Assurance staff.

IMPLEMENT CHANGES – EDUCATION / QUALITY ASSURANCE STAFF

5.19 The Education / Quality Assurance staff will conduct all Implementation procedures for both Emergency and Normal changes with the understanding that Emergency Changes are expedited regardless of impact to other activities ongoing in the CC CTO.

5.20 If the change is initiated from inside the CTO the Education / Quality Assurance staff will engage business partners impacted by the change to assess the impact to business partners.

5.21 The Education / Quality Assurance staff will prepare an implementation plan including:

5.21.1 SOP and Guideline Changes needed

5.21.2 Communication plan to ensure all impacted parties receive education / training

5.21.3 Identify all other activities required to implement the change

5.21.4 A target date for the implementation of the change

5.22 The Education / Quality Assurance staff will communicate the implementation plan to the CTO AD and the Change Initiator. If the change is an Emergency Change then the Appropriate Leadership will be informed as well.

5.23 If the Change Initiator does not find the implementation plan acceptable the Education/Quality Assurance staff will escalate the issue to the CTO AD.

5.24 If the CTO AD is unable to resolve issues with the implementation plan the CTO AD will use the change approval process to resolve the issues.

5.25 If the implementation plan is accepted by the Change Initiator the plan will be executed.

5.26 If the change is initiated from inside the CTO the Education / Quality Assurance staff will post the change on the Cancer Center website with the implementation plan.

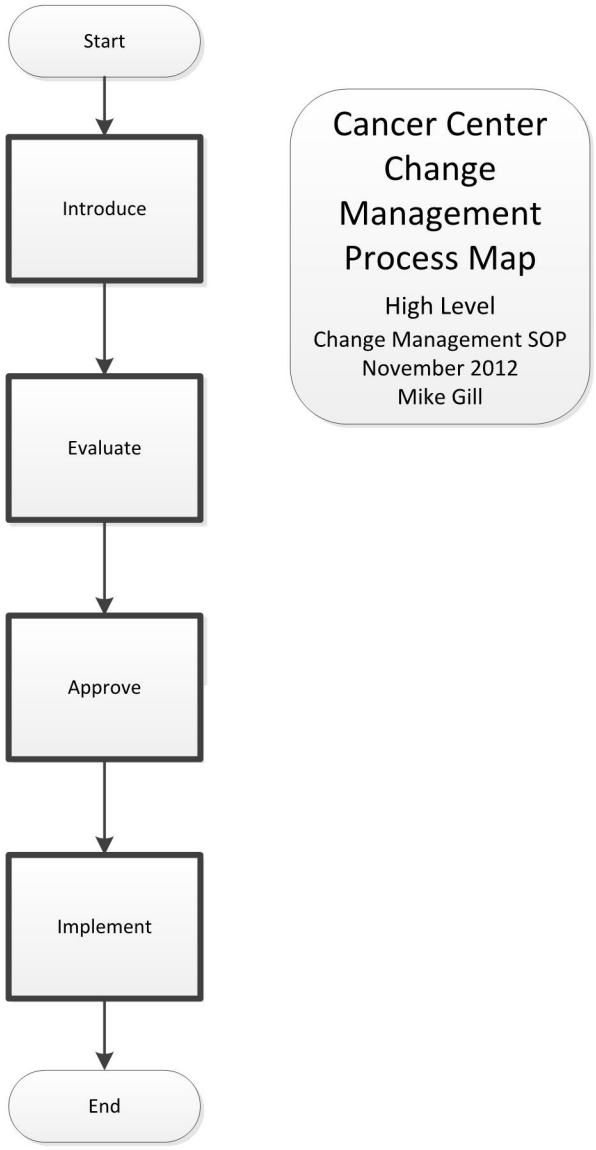
5.27 All completed changes will be communicated to the CTO AD and the Change Initiator. If the change is an Emergency Change the Appropriate Leadership will be notified as well. This Normal change completion may be communicated through standing meetings if they exist.

6.0 REFERENCES

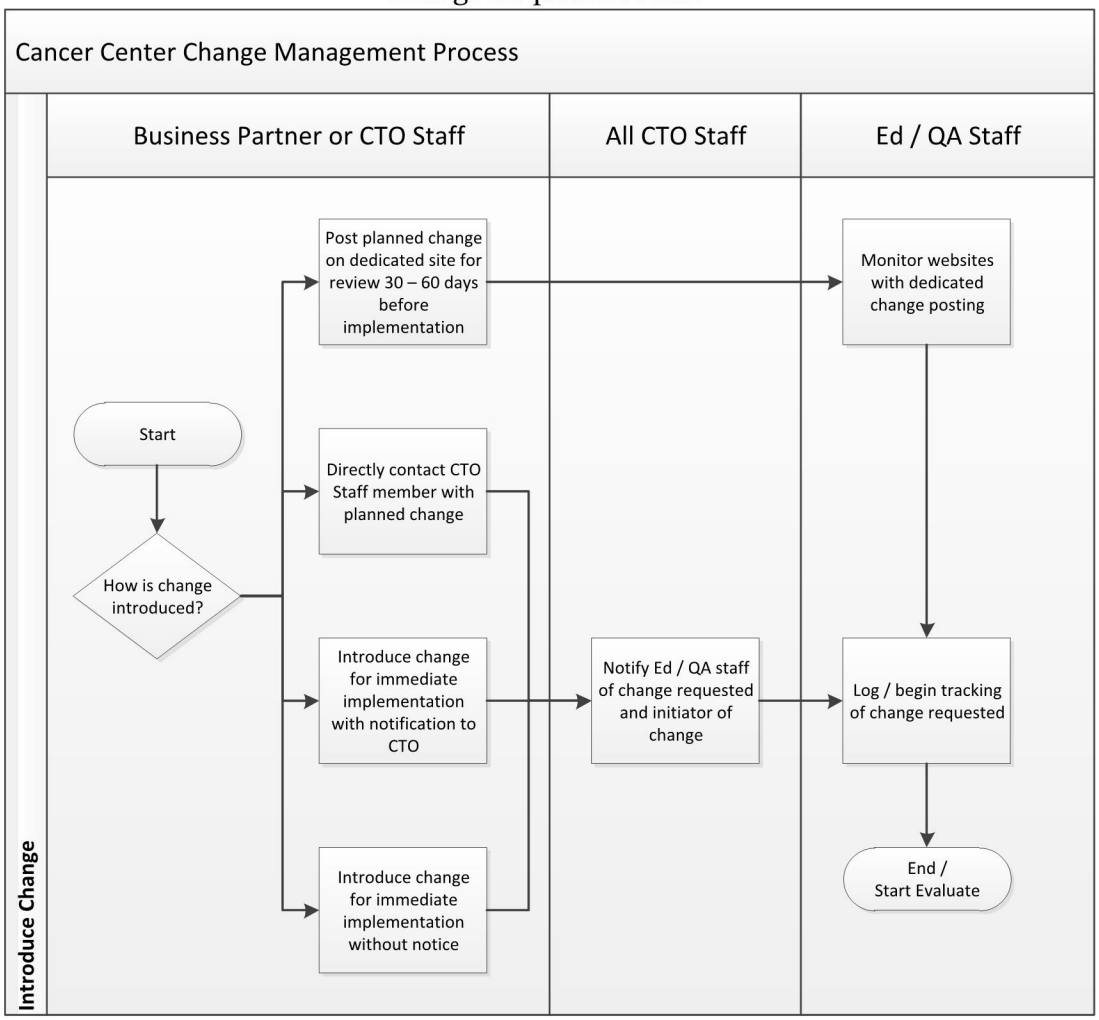
None

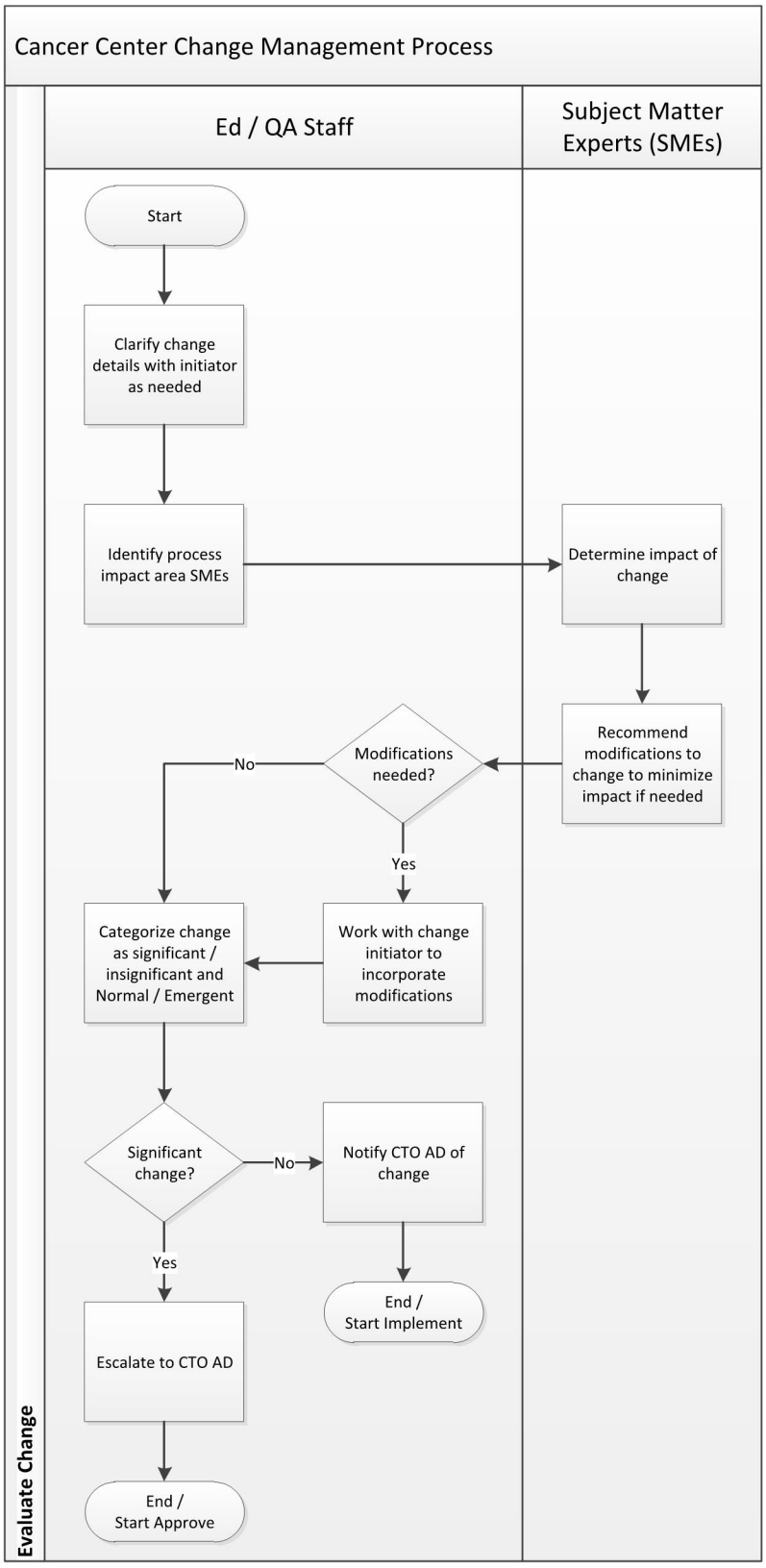
7.0 APPENDICES

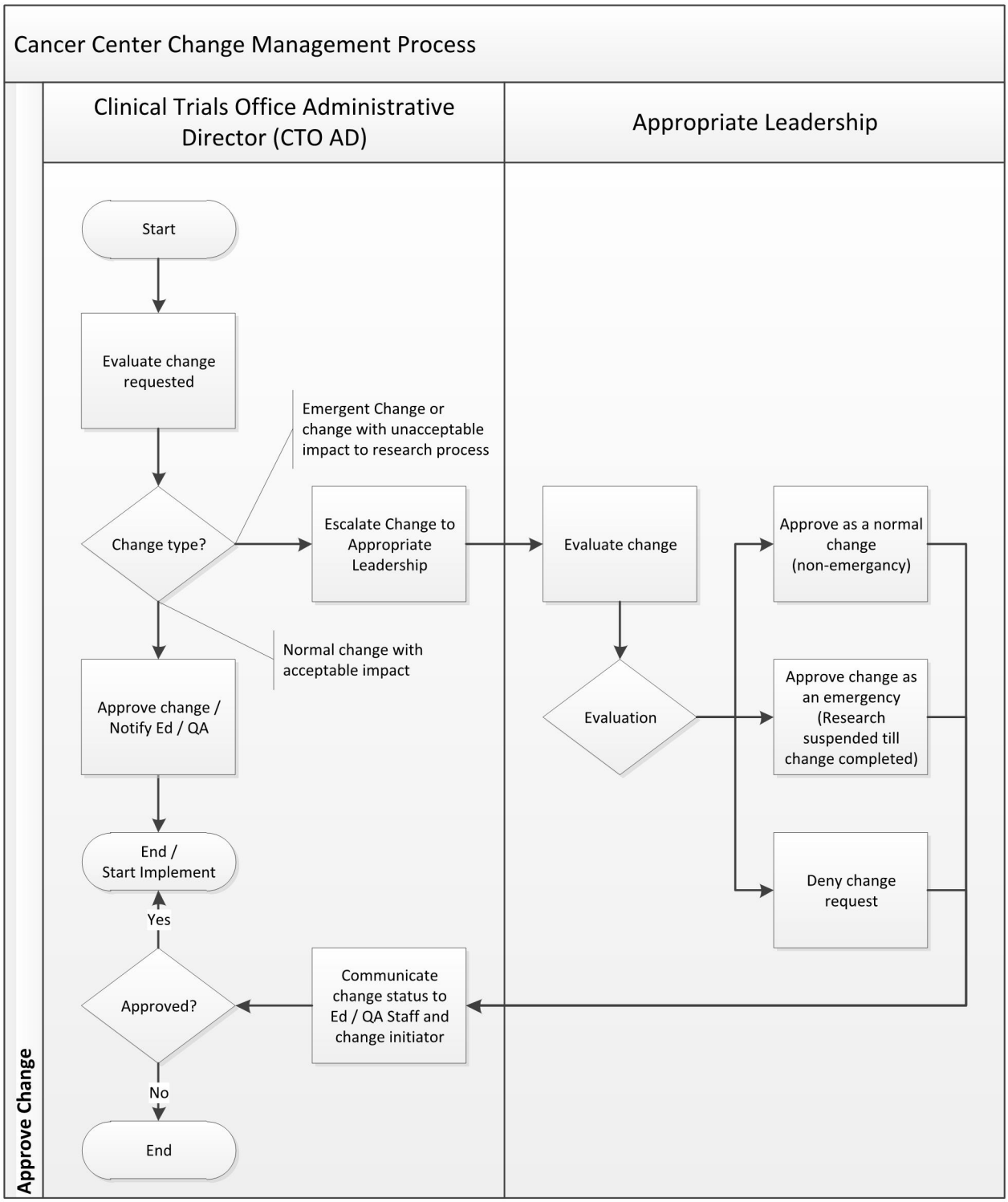
Change Management Process Map

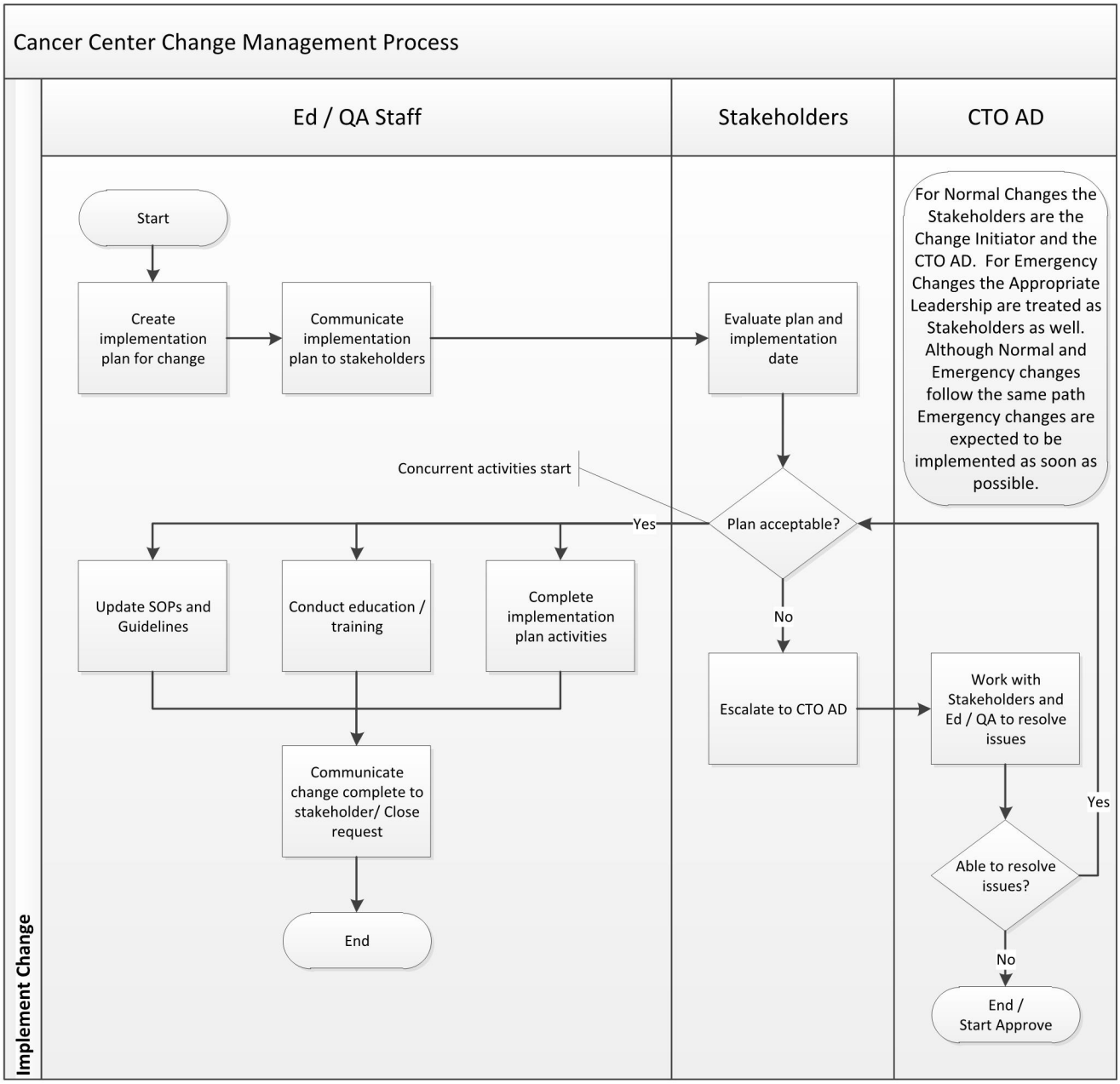


Change Request Process









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CCCTO Administrative Director

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

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Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.