


DukeMedicine


Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

DOCUMENT NUMBER: COMM-PAS-025 FRM1

DOCUMENT TITLE:

MasterControl HTML Form Verification Request

DOCUMENT NOTES:
Document Information
Revision: 01

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Control Information
Author: MC363

Owner: MC363

Previous Number: None

Change Number: PAS-CCR-043

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

STEP 1 PRE-APPROVAL			
Verification Request #:		Date of Request:	Requestor:
☐ New Form in MasterControl ☐ Revision to Existing Form		CCR#(s):	Current Released HTML Form Version #:
MasterControl Document/Form #:		Current MasterControl Version #:	MasterControl Document/Form Title:
Description of Changes of the Form (Refer to CCR):			
Do the Change(s) Involve/Impact: Title of the Form ☐ No ☐ Yes Reporting/Datasets (changes to Existing Field/Tab Names, adding or deleting Fields, adding or deleting Tabs) ☐ No ☐ Yes Functionality of the Form (changes to Check Boxes, Radio Buttons, Select Boxes, File Selection Boxes, Save and Submission buttons, etc.) ☐ No ☐ Yes Review/Approval Process (changes to the review and approval process of this form) ☐ No ☐ Yes Others: _____ ☐ N/A			
Comment:			

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

Description of the Functional Requirements/Specifications and Acceptance Criteria of the Verification/Validation:		
Number	Verification/Validation Items	Acceptance Criteria
1.	Verify the HTML form against the PDF form to ensure that the contents on both forms are identical	The contents of the HTML form and the PDF form should be identical.
2.	Compare the label of each tab on the HTML form to the relevant header of each section on the PDF form to ensure the labels and the relevant headers match	The label of each tab on the HTML form should match the relevant header of each section on the PDF form.
3.	Check the functionality of the HTML form, such as character limitation in Text Field and Text Area, Check Boxes, Radio Buttons, Date Selection from the Calendar, Select Boxes, Select from the drop-down list, File Selection Boxes in the Attachment Field, Save and Submission Buttons, etc.	The form should meet the pre-defined functional requirements.
4.	Test the review/approval Process of the form	The form should be routed per the defined specific approval process for each form.
5.	Verify that the planned implementation date of the HTML form matches the due date for the associated training InfoCard training task.	The planned implementation date of the HTML form matches the due date for the associated training InfoCard training task.
6.	Other:	
Comment:		
Requestor (Author/Initiator, or Designee)		☐ Requirements Reviewed/Understood
MasterControl HTML Form Developer		☐ Requirements Reviewed/Understood
CQP Director or Designee		☐ Pre-approved

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

STEP 2. TESTING SITE VERIFICATION/VALIDATION					
<i>*Attach any printed copies of the test forms **Author/Initiator (or Designee), HTML Form Developer, and CQP serve as Testers</i>					
Verification Request #:			Date Released to Testing Site:		
Tester	Name/Initials	Date Completed	Pass	Fail – Select, Add Item # from page 2, and describe the issue below	
A			☐	☐ Item(s) #	
B			☐	☐ Item(s) #	
C			☐	☐ Item(s) #	
Completed by Tester(s)					
Item #	Description of Issue(s)			Initials/Date	
Comment:					
Completed by MasterControl HTML Form Developer					
Item#	Description of Further Change(s) Made			Initials/Date	
Completed by MasterControl HTML Form Change Owner and CQP					
Verification that the planned implementation date of the HTML form matches the due date for the associated training InfoCard training task					
☐ No ☐ Yes					

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

Initials/Date (Author/Initiator):		
Initials/Date (CQP):		
Comment:		
Author/Initiator (or Designee)	Date:	☐ Pass; Approved for Release to Production Site. ☐ Fail; Forward to MasterControl HTML Form Developer
CQP Tester	Date:	☐ Pass; Approved for Release to Production Site. ☐ Fail; Forward to MasterControl HTML Form Developer
MasterControl HTML Form Developer	Date:	☐ Further Changes Made, Ready for Testing Site Re-verification/validation ☐ Reviewed; Ready for Production Site Release

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

STEP 2a. TESTING SITE RE-VERIFICATION/RE-VALIDATION (Further Changes Have been Made, Ready for Re-verification/Re-validation, may be repeated as needed)				
* Attach any printed copies of the test forms **Author/Initiator (or Designee), HTML Form Developer, and CQP serve as Testers				
☐ N/A Initial Testing Passed, all Functional Requirements/Acceptance Specifications have been met.				
Verification Request#:		Date Released to Testing Site:		
Tester	Name/Initials	Date Completed	Pass	Fail – Select, Add Item # from page 2, and describe the issue below
A			☐	☐ Item(s) #
B			☐	☐ Item(s) #
C			☐	☐ Item(s) #
Completed by Tester(s)				
Item #	Description of Issue(s)			Initials/Date
Comment:				
Completed by MasterControl HTML Form Developer				
Items#	Description of Further Change(s) Made			Initials/Date
Completed by MasterControl HTML Form Change Owner and CQP				
Verification that the planned implementation date of the HTML form matches the due date for the associated training InfoCard training task				
☐ No ☐ Yes				

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

Initials/Date (Author/Initiator):		
Initials/Date (CQP):		
Comment:		
Author/Initiator (or Designee)	Date:	☐ Pass; Approved for Release to Production Site. ☐ Fail; Forward to MasterControl Form Developer. Attach additional Testing Site Verification/Validation
CQP Tester	Date:	☐ Pass; Approved for Release to Production Site. ☐ Fail; Forward to MasterControl Form Developer. Attach additional Testing Site Verification/Validation
MasterControl HTML Form Developer	Date:	☐ Further changes made; Ready for Testing Site Re-verification/Re-validation ☐ Reviewed; Ready for Production Site Release

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1
MasterControl HTML Form Verification Request

STEP 3. PRODUCTION SITE VERIFICATION/VALIDATION					
<i>*Attach any printed copies of the test forms ** Author/Initiator (or Designee), HTML Form Developer, and CQP serve as Testers</i>					
Verification Request #:			Date Released to Production Site:		
Tester	Name/Initials	Date Completed	Pass	Fail – Select, Add Item # from page 2, and describe the issue below	
A			☐	☐ Item(s) #	
B			☐	☐ Item(s) #	
C			☐	☐ Item(s) #	
Completed by Tester(s)					
Item #	Description of Issue(s)			Initials/Date	
Comment:					

Verification Request #: 20XX-XXXX

COMM-PAS-025 FRM1

MasterControl HTML Form Verification Request

STEP 4 POST-APPROVAL		
* Attach any printed copies of the test forms, DEV, CAPA, new CCR, new HTML form verification request, as available.		
Requestor (Author/ Initiator, or Designee)	Date:	☐ Approved ☐ Approved for Continual Use, but Revision Recommended ☐ Failed; Forward to MasterControl HTML Form Developer. Submit a New CCR and a New HTML Form Verification Request. Initiate a DEV/INV Report. Initiate a CAPA, if applicable. Attach all associated documents, as available. New CCR# _____ New Verification Request#: _____ DEV#: _____ CAPA#: _____
MasterControl HTML Form Developer	Date:	☐ Reviewed and Approved ☐ Failed; Assist with CAPA as Needed. Make Changes to the HTML Form. New Form Verification/Validation Request pending.
CQP Director or Designee	Date:	☐ Approved ☐ Approved for Continual Use, but Revision Recommended ☐ NOT Approved Comments:

Signature Manifest**Document Number:** COMM-PAS-025 FRM1**Revision:** 01**Title:** MasterControl HTML Form Verification Request**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-022 -- COMM-PAS-027 JA1**Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 12:01:08 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Kris Mahadeo (KM193)		26 Jun 2025, 10:34:13 AM	Approved

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Name/Signature	Title	Date	Meaning/Reason
Kris Mahadeo (KM193)		26 Jun 2025, 10:34:28 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 05:14:55 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:51:48 PM	Approved