

**DUKE****DOCUMENT NUMBER:** COMM-QA-082 FRM1**DOCUMENT TITLE:**

MasterControl HTML Form Verification Request FRM1

**DOCUMENT NOTES:****Document Information****Revision:** 02**Vault:** COMM-QA-rel**Status:** Release**Document Type:** COMM-QA**Date Information****Creation Date:** 03 Nov 2021**Release Date:** 11 Nov 2021**Effective Date:** 11 Nov 2021**Expiration Date:****Control Information****Author:** BS76**Owner:** BS76**Previous Number:** COMM-QA-082 FRM1 Rev 01 **Change Number:** COMM-CCR-195

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### MASTERCONTROL HTML FORM VERIFICATION REQUEST FRM1

<b>STEP 1 PRE-APPROVAL</b>					
<b>Verification Request #:</b>		<b>Date of Request:</b>		<b>Requestor:</b>	
<input type="checkbox"/> <b>New Form in MasterControl</b>		<input type="checkbox"/> <b>Revision to Existing Form</b>		<b>CCR#(s):</b>	
<b>MasterControl Document/Form #:</b>		<b>Current MasterControl Version #:</b>		<b>Current Released HTML Form Version #:</b>	
<b>MasterControl Document/Form Title:</b>		<b>Current MasterControl Version #:</b>		<b>MasterControl Document/Form Title:</b>	
<b>Description of Changes of the Form (Refer to CCR):</b>					
<b>Do the Change(s) Involve/Impact:</b> <b>Title of the Form</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>Reporting/Datasets (changes to Existing Field/Tab Names, adding or deleting Fields, adding or deleting Tabs)</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>Functionality of the Form (changes to Check Boxes, Radio Buttons, Select Boxes, File Selection Boxes, Save and Submission buttons, etc.)</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>Review/Approval Process (changes to the review and approval process of this form)</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>Others:</b> <div style="border-bottom: 1px solid black; width: 50%; display: inline-block;"></div> <input type="checkbox"/> N/A					
<b>Comment:</b>					

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<b>Description of the Functional Requirements/Specifications and Acceptance Criteria of the Verification/Validation:</b>		
<b>Number</b>	<b>Verification/Validation Items</b>	<b>Acceptance Criteria</b>
<b>1.</b>	Verify the HTML form against the PDF form to ensure that the contents on both forms are identical	The contents on the HTML form and the PDF form should be identical.
<b>2.</b>	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.
<b>3.</b>	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 list, File Selection Boxes in the Attachment Field, Save and Submission Buttons, etc.	The form should meet the pre-defined functional requirements.
<b>4.</b>	Test the review/approval Process of the form	The form should be routed per defined specific approval process for each form.
<b>5.</b>	Verify that planned implementation date of HTML form matches the due date for the associated training InfoCard training task.	The planned implementation date of HTML form matches the due date for the associated training InfoCard training task.
<b>6.</b>	Other:	
<b>Comment:</b>		
<b>Requestor (Author/Initiator, or Designee)</b>	<b>Date:</b>	<input type="checkbox"/> <b>Requirements Reviewed/Understood</b>
<b>MasterControl HTML Form Developer</b>	<b>Date:</b>	<input type="checkbox"/> <b>Requirements Reviewed/Understood</b>
<b>QSU Director or Designee</b>	<b>Date:</b>	<input type="checkbox"/> <b>Pre-approved</b>

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

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 Durham, NC

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### MASTERCONTROL HTML FORM VERIFICATION REQUEST FRM1

<b>Initials/Date (Author/Initiator):</b>  <b>Initials/Date (QSU):</b>		
<b>Comment:</b>		
<b>Author/Initiator (or Designee)</b>	<b>Date:</b>	<input type="checkbox"/> <b>Pass; Approved for Release to Production Site.</b> <input type="checkbox"/> <b>Fail; Forward to MasterControl HTML Form Developer</b>
<b>QSU Tester</b>	<b>Date:</b>	<input type="checkbox"/> <b>Pass; Approved for Release to Production Site.</b> <input type="checkbox"/> <b>Fail; Forward to MasterControl HTML Form Developer</b>
<b>MasterControl HTML Form Developer</b>	<b>Date:</b>	<input type="checkbox"/> <b>Further Changes Made, Ready for Testing Site Re-verification/Re-validation</b> <input type="checkbox"/> <b>Reviewed; Ready for Production Site Release</b>

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### MASTERCONTROL HTML FORM VERIFICATION REQUEST FRM1

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

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### MASTERCONTROL HTML FORM VERIFICATION REQUEST FRM1

<b>Initials/Date (Author/Initiator):</b>  <b>Initials/Date (QSU):</b>		
<b>Comment:</b>		
<b>Author/Initiator (or Designee)</b>	<b>Date:</b>	<input type="checkbox"/> <b>Pass; Approved for Release to Production Site.</b> <input type="checkbox"/> <b>Fail; Forward to MasterControl Form Developer.</b> Attach additional Testing Site Verification/Validation
<b>QSU Tester</b>	<b>Date:</b>	<input type="checkbox"/> <b>Pass; Approved for Release to Production Site.</b> <input type="checkbox"/> <b>Fail; Forward to MasterControl Form Developer.</b> Attach additional Testing Site Verification/Validation
<b>MasterControl HTML Form Developer</b>	<b>Date:</b>	<input type="checkbox"/> <b>Further changes made; Ready for Testing Site Re-verification/Re-validation</b> <input type="checkbox"/> <b>Reviewed; Ready for Production Site Release</b>

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



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<b>STEP 4 POST-APPROVAL</b>		
<i>* Attach any printed copies of the test forms, DEV, CAPA, new CCR, new HTML form verification request, as available.</i>		
<b>Requestor (Author/ Initiator, or Designee)</b>	<b>Date:</b>	<input type="checkbox"/> <b>Approved</b> <input type="checkbox"/> <b>Approved for Continual Use, but Revision Recommended</b> <input type="checkbox"/> <b>Failed; Forward to MasterControl HTML Form Developer.</b> 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. <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <span>New CCR# _____</span> <span>New Verification Request#: _____</span> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <span>DEV#: _____</span> <span>CAPA#: _____</span> </div>
<b>MasterControl HTML Form Developer</b>	<b>Date:</b>	<input type="checkbox"/> <b>Reviewed and Approved</b> <input type="checkbox"/> <b>Failed; Assist with CAPA as Needed.</b> Make Changes to the HTML Form. New Form Verification/Validation Request pending.
<b>QSU Director or Designee</b>	<b>Date:</b>	<input type="checkbox"/> <b>Approved</b> <input type="checkbox"/> <b>Approved for Continual Use, but Revision Recommended</b> <input type="checkbox"/> <b>NOT Approved</b> <b>Comments:</b> <div style="height: 100px; border: 1px solid black; margin-top: 5px;"></div>

**Signature Manifest****Document Number:** COMM-QA-082 FRM1**Revision:** 02**Title:** MasterControl HTML Form Verification Request FRM1**Effective Date:** 11 Nov 2021

All dates and times are in Eastern Time.

**COMM-QA-082 FRM1 MasterControl HTML Form Verification Request FRM1****Author**

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Bing Shen (BS76)		09 Nov 2021, 12:55:24 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		09 Nov 2021, 01:33:55 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Linda Shaw (LAS151)		10 Nov 2021, 09:48:28 AM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		10 Nov 2021, 01:35:47 PM	Approved