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

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MasterControl HTML Form Implementation Procedure

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COMM-PAS-025
MasterControl HTML Form Implementation Procedure

1 PURPOSE

1.1 To describe the procedure for verifying a new MasterControl HTML form, or an existing MasterControl HTML form to which a change has been made to ensure that the HTML form has been built according to the requirements and meets the defined acceptance specifications.

1.2 To describe the procedure for verifying and validating a new MasterControl HTML form, or an existing MasterControl HTML form to which a change has been made to ensure that the HTML form meets the functional requirements and expectations.

2 INTRODUCTION

2.1 MasterControl is a validated, 21 CFR Part 11 compliant document management system and is a primary document management system utilized by Duke Programs.

2.2 MasterControl Process automates, streamlines, and effectively manages interactive form-based processes to help ensure compliance with FDA regulations with electronic records. Forms in HTML format are built in the MasterControl Process module, also referred to as "Forms". Verification and validation of a new HTML form, or an existing MasterControl HTML form to which a change has been made, are required in both the Testing and Production sites.

2.3 MasterControl usernames and passwords are designated for access to the MasterControl Testing and Production sites. The Testing site username and password are different from the username and password for the Production site.

2.4 Any changes made to the MasterControl system requires a Change Control Request (CCR), and the changes are reviewed and approved through a proper change control process. Select Medical Director, the Clinical Quality Program (CQP), the Document Control System staff, and all personnel involved in initiating, completing, evaluating, and approving changes via the change control process are responsible for ensuring the requirements defined in the COMM-PAS-004 *Change Control* are met.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure is referenced when verifying and validating a new MasterControl HTML form or an existing MasterControl HTML form to which a change has been made in both the Testing and Production sites. This procedure applies to the author/initiator of the requested change, the MasterControl Personnel, CQP, the Program Supervisor and/or Manager, and Training Coordinator, as applicable.

NOTE: The author/initiator of the requested change must communicate the updates to the MasterControl Personnel, the Clinical Quality Program (CQP), the

Program Supervisor and/or Manager, and Training Coordinator, as applicable, throughout the full verification and validation processes.

3.1.1 The procedure for requesting a new form and revision to an existing form is described in COMM-PAS-004 *Change Control*.

3.1.2 The procedure for requesting verification and validation of a new MasterControl HTML form, or an existing MasterControl HTML form to which a change has been made, is described in this document as follows. Refer to the flowchart in COMM-PAS-025 JA1 *MasterControl HTML Form Verification*, as needed.

3.2 COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* is used to document the pre-approval and post-approval of the verification/ validation request, to document the verification/validation testing performed in both the Testing and Production sites, and to document verification/alignment of the HTML effective dates with the associated training tasks.

3.3 All personnel involved with the review, execution, and approval of HTML form verification and validation are responsible for training on this document and the associated form and complying with the requirements of this procedure.

RESPONSIBILITIES

Author/Initiator (or designee) (Required)	• Identifies the need to make changes to the existing form or create a new form/dataset • Upon identifying the need for HTML updates, engage the CQP, Supervisor, Manager, and the Division Chiefs, as applicable, to ensure appropriate evaluation from Quality, Operations, and Management, prior to implementation • Initiates COMM-PAS-004 FRM1 *Change Control Request (Effectiveness Check)* • Initiates COMM- PAS-025 FRM1 *MasterControl HTML Form Verification Request.* • Develops a new form in WORD format, or makes changes to the existing form in WORD format maintained in MasterControl ***NOTE**: The form in WORD format will be published in PDF format once the collaboration in MasterControl is ended* • Serves as one of the verifiers/testers and executes the verification and validation to ensure that the defined acceptance specifications and functional requirements are met • Documents problems/issues on COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request*, as applicable

RESPONSIBILITIES

	• Communicates issues to the MasterControl Personnel, CQP, and Program Supervisor/Manager, as applicable • Communicates to MasterControl Personnel, CQP, Program Supervisor/Manager, and Training Coordinator, if applicable (e.g., instructions, changes, dates for release to Testing and Production sites, and verification status) • Attaches the scanned copy of the required section of COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* to the CCR in each route. Refer to Appendix I.
MasterControl Personnel (HTML form developer, Required)	• Reviews and understands the requirements and specifications defined in the form-specific COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* • Develops and builds the MasterControl HTML form according to the requirements and specifications defined in the template in PDF format • Executes the verification and validation and serves as one of the verifiers/testers to ensure that the defined acceptance specifications and functional requirements are met • Documents problems/issues on COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* • Communicates issues to the Author/Initiator, CQP, and Program Supervisor/Manager, if applicable
CQP (Required) ***Note**: The CQP member who reviews and approves the Verification Request should not execute the Verification/Validation.*	• Collaborates with the author/initiator to ensure the form in MasterControl collaboration meets the defined requirement and specification. • Reviews and pre-approves COMM- PAS-025 FRM1 *MasterControl HTML Form Verification Request* • Approves the associated CCR • Executes the verification and validation and serves as one of the verifiers/testers to ensure that the defined specifications and functional requirements are met • Documents problems/issues on COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request*

RESPONSIBILITIES

	• Communicates issues to the Author/Initiator, MasterControl Personnel, and Program Supervisor/Manager, if applicable • Reviews COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* for completeness and issues final approval • Verifies that the scanned copy of the required section of COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* has been attached to the CCR in each route. Refer to Appendix I.

4 DEFINITIONS/ACRONYMS

4.1 21CFR Part 11 – Federal regulations that considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records.

4.2 CAPA – Corrective and Preventive Actions

4.3 CCR – Change Control Request

4.4 CQP – Clinical Quality Program

4.5 DCS – Document Control System

4.6 HTML – (Hypertext Markup Language) is the standard markup language for documents designed to be displayed in a web browser.

4.7 MasterControl– An electronic document management system which is 21 CFR Part 11 compliant ("Electronic Records; Electronic Signatures"). The software allows storage of electronic documents and records, collaboration, document approval routing, and document training.

4.8 QA – Quality Assurance

4.9 SQIPP – Safety, Quality, Identity, Potency and Purity

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 Computer access to MasterControl

6.2 MasterControl is validated using Firefox and Chrome.

6.2.1 Do not use Internet Explorer (IE) or Microsoft EDGE

7 SAFETY

7.1 Maintain confidentiality when working with patient health information

8 PROCEDURE

8.1 Before an author/initiator develops a new form or makes a change to an existing form maintained in MasterControl, a change control request (CCR) documented on the COMM-PAS-004 FRM1 *Change Control Request (Effectiveness Check) FRM1* must be submitted, and the CCR plan must be approved in MasterControl. Refer to COMM-PAS-004 *Change Control.*

8.1.1 Requirements of HTML form verification and validation must be noted on CCR in the Impact/Risk Assessment section.

8.1.2 Proposed changes and CCRs are presented to alert cross-functional groups of the changes and to assess the impact/risk of the change(s), if applicable.

8.2 Prior to submitting the CCR for plan approval, COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* must be submitted by the author/initiator to the MasterControl HTML form developer and CQP for review and/or pre-approval. The pre-approved COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* must be attached to the CCR before the CCR is submitted for plan approval. Refer to Appendix I.

8.3 Additionally, author/initiators should discuss the applicable change(s) with the appropriate team members, as applicable per program, to ensure a cross-functional review of the proposed HTML form creation or modifications. When applicable, this assessment should be noted in the associated Change Control.

8.4 Once the CCR plan is approved, the author/initiator can start developing the new form or can make change(s) to the existing form in MasterControl. The MasterControl HTML form developer will build the HTML form based on the finalized form template in PDF format. Additionally, the change owner and Quality will verify that the effective date of the associated HTML form is aligned and mimics the date applied to the due date of the document training InfoCard. If these dates do not align, contact the supervisor and the training coordinator prior to advancing further in the verification/validation test.

8.5 MasterControl HTML form developer communicates directly to the author/initiator (or designee) and CQP when the HTML form is ready to be released to the Test site for testing.

8.5.1 The author/initiator (or designee), MasterControl HTML form developer, and CQP complete the initial verification and validation as defined on COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* and document any issues or concerns. All the identified issues or concerns should be communicated directly to the MasterControl HTML form developer.

8.5.2 If there are any issues identified during the verification/validation process, the HTML form developer will make further changes to the form based on the identified issues and release the HTML form to the Test site for reverification/revalidation.

8.5.3 The HTML form will be released to the Production site if all the defined functional requirements and acceptance specifications are met after completion of the reverification and revalidation. Refer to section 8.6 and below.

8.5.4 If there are any issues identified during the reverification/revalidation process, above steps defined in section 8.5.2 should be repeated. There is no limitation on the number of repetitions of executions of verification/ validation in the Test site.

8.6 After the Test site verification/validation passes, the author/initiator should attach the completed testing site verification/validation documents to the CCR and submit the CCR for CQP approval to implement the requested change (s) and coordinate the Production site release date with the MasterControl HTML form developer. MasterControl HTML form developer communicates directly to the author/initiator (or designee) and CQP when the HTML form is ready to be released to the Production site.

8.6.1 The author/initiator communicates the planned Production site release date to applicable personnel, e.g., end users in all applicable departments, verifiers, MasterControl System Administrator, CQP, and the Training Coordinator.

8.7 When the HTML form is released to the Production site, the author/initiator (or designee), MasterControl HTML form developer, and CQP should complete the verification and validation as defined on COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* as soon as possible and document any issues or concerns. Ideally, this should be done on the day of release. All the identified issues or concerns should be communicated directly to the MasterControl HTML form developer.

8.7.1 The verification/validation in the Production site should only be performed once.

8.7.2 If there is any issue identified during the verification and validation process in the Production site, the author/initiator, the MasterControl HTML form developer, CQP, and the Program Supervisor/Manager, if applicable, should collaboratively assess the impact due to the identified issue(s) and document the assessment on the COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request*.

8.7.2.1 If the identified issue has the potential for compromising data integrity and/ or product Safety, Quality, Identity, Potency, and Purity (SQIPP), this requires immediate investigation and resolution.

8.7.2.1.1 COMM-PAS-013 FRM1 *Deviation and Investigation Report* should be initiated in a timely manner to document the investigation of this event. Refer to COMM-PAS-013 *Deviations and Investigations*.

8.7.2.1.2 COMM-PAS-015 FRM1 *CAPA Report* should be initiated, if applicable, to document the corrective and preventive actions taken to mitigate the risk. Refer to COMM-PAS-015 *Corrective and Preventive Actions*.

8.7.2.1.3 A new CCR and a new COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* should be initiated to document the requested change(s), and the verification and validation process after the HTML form developer fixes the issue(s) identified during the Production site verification/validation.

8.7.2.1.4 The document numbers of the Deviation and Investigation Report, the CAPA Report, if applicable, the new CCR, and the new COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* must be reflected on the current COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request*.

8.7.2.2 If the identified issue is determined to be very minor and there is no potential for compromising the data integrity and the product SQIPP, the CQP can either approve the HTML form for continual use in the Production site until the next revision, or recommend the author/initiator to initiate a new CCR to request changes made to the HTML form. The verification and validation process must be repeated in both the Test site and the Production site if a new CCR is initiated.

8.8 Once the verification and validation in the Production site are completed and the HTML form meets all the functional requirements and the defined acceptance specifications, the COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* should be submitted to CQP for post-approval, i.e., final approval.

8.8.1 It should be noted that the CQP member who reviews and approves the COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* should not execute the HTML form verification/validation.

8.9 Once the post-approval is completed, the COMM-PAS-025 FRM1 *MasterControl HTML Form Verification Request* must be scanned and attached to the associated CCR by the author/initiator as part of the outcome of the effectiveness check prior to CCR final approval.

8.10 After release of the HTML form to the MasterControl Production site, any additional or new changes that are identified must go through this same process, beginning with the initiation of a CCR, Section 8.1.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-004 Change Control

9.2 COMM-PAS-004 FRM1 Change Control Request (Effectiveness Check)

9.3 COMM-PAS-025 FRM1 MasterControl HTML Form Verification Request

9.4 COMM-PAS-025 JA1 MasterControl HTML Form Verification

9.5 COMM-PAS-013 Deviations and Investigations

9.6 COMM-PAS-013 FRM1 Deviation and Investigation Report

9.7 COMM-PAS-015 Corrective and Preventive Actions

9.8 COMM-PAS-015 FRM1 CAPA Report

10 REFERENCES

10.1 21CFR Part 11 Electronic Records; Electronic Signatures

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	• New document

Appendix I

HTML Form Verification Request Requirements for CCR Routing

CCR Route	**Attach HTML Form Verification Request Completed through:**
CCR Plan Review Route (Route 1)	Step 1 Pre-Approval
Implementation Approval Route (Route 2)	Step 2 Testing Site Verification/Validation
Effectiveness Check Review Route (Route 3)	Step 3 Production Site Verification/Validation Step 4 Post-Approval

Signature Manifest

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