


**Duke**Medicine


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

**DOCUMENT NUMBER:** COMM-PAS-026

**DOCUMENT TITLE:**

Document Control Procedures for MasterControl

**DOCUMENT NOTES:**
**Document Information**
**Revision:** 01

**Vault:** COMM-PAS-rel

**Status:** Release

**Document Type:** COMM-PAS

**Date Information**
**Creation Date:** 20 Jun 2025

**Release Date:** 01 Jul 2025

**Effective Date:** 01 Jul 2025

**Expiration Date:**
**Control Information**
**Author:** MC363

**Owner:** MC363

**Previous Number:** None

**Change Number:** PAS-CCR-043

## **COMM-PAS-026**

### **Document Control Procedures for MasterControl**

#### **1 PURPOSE**

- 1.1 This procedure describes the process for creating, launching, tracking, checking out/checking in, approving, publishing, issuing, and archiving of controlled Document InfoCards in MasterControl (MC).

#### **2 INTRODUCTION**

- 2.1 The document management system, MasterControl, will establish, document, and maintain records that encompass the requirements listed in this procedure.

#### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 This procedure covers the processes required to effectively control quality documentation in MasterControl.
- 3.2 This procedure will apply to any document/record maintained in MasterControl.

#### **4 DEFINITIONS/ACRONYMS**

- 4.1 SysAdmin (System Administrator) – The person or position responsible for the administration, configuration, and control of the MC software.
- 4.2 MasterControl (MC) – A validated software product from MasterControl, Inc., which is used as the main document control agent in the automation and control of document approval, change control, and distribution processes.
- 4.3 MasterControl Portal – Provides the functions needed to set up and maintain the MasterControl quality suite applications.
- 4.4 InfoCard – MasterControl functionality to collect header or metadata related to each document stored in the system. This header or metadata is then used by the system to organize, store, and retrieve files.
- 4.5 Packet Task – The vehicle that carries an object or group of objects through an approval cycle.
- 4.6 Route – A route is the workflow component of a task composed of a series of steps, which include a predefined sequence of users who must act upon the task contents.
- 4.7 Lifecycle – The Status that a document is in from the time it is created until it is archived. Documents will have three steps or statuses within its Lifecycle. These include Draft, Release, and Archive.
- 4.8 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are usually of three (3) common types: Draft, Release, and Archive.
- 4.9 Collaboration – Sending a document for review and redlining prior to approval.
- 4.10 DCS – Document Control System

## 5 MATERIALS

5.1 NA

## 6 EQUIPMENT

6.1 Hardware/Software

6.1.1 Computer to access MasterControl.

## 7 SAFETY

7.1 NA

## 8 PROCEDURE

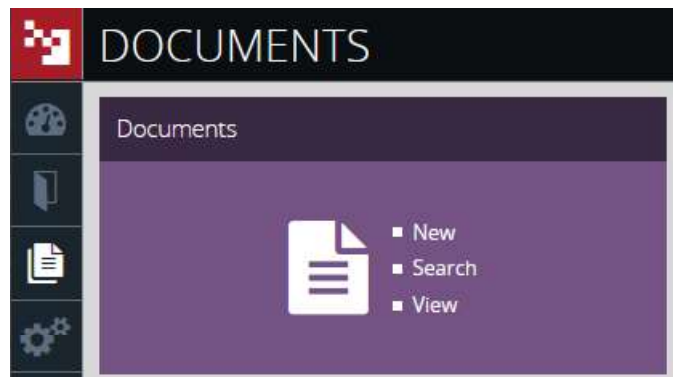
8.1 New Document in MasterControl

8.1.1 Creating a Document InfoCard

**NOTE:** Data entry fields **do not** accept the following characters:

‘ “ & < > ^

8.1.2 From the navigation menu, click on **Documents**. Click **New**.



8.1.2.1 The **Add a New Document** window displays.

8.1.2.2 Select InfoCard Type and InfoCard Subtype

8.1.2.3 Optional: Drag and drop the main file; click **CONTINUE**.

8.2 Sections of an InfoCard

8.2.1 Version Information

8.2.1.1 In the **Document Number** field, the selected InfoCard Type/Subtype automatically populates with a numbering scheme and appears in the **Document Number** field.

**NOTE:** Preset InfoCard numbers are directly linked to specific InfoCard Types/Subtypes.

8.2.1.2 If a preset number is not needed, manually record a document number.

8.2.1.3 The **Revision** field will automatically populate starting at 01.

8.2.1.4 The **Version** field will automatically populate and is grayed out. **NOTE:** A new version appears each time a *new* main file is uploaded to the InfoCard.

8.2.1.5 The **Vault/Lifecycle/Document InfoCard Type/Subtype** fields pre-populate.

8.2.1.6 In the **Title** field, enter document title (300-character limit).

8.2.1.7 The **Notes** field is not required but is useful to record pertinent information for tracking (2,000-character limit).

**NOTE:** The **Status** of the InfoCard is reflected above the Vault/Lifecycle fields.

## 8.2.2 Other Information

8.2.2.1 In the **Author** and **Owner** fields, select the appropriate name from the drop-down lists.

**NOTE:** Even though these fields are not required fields, it is essential in identifying, at minimum, the **document author**.

8.2.2.2 In the **Previous Number** field, manually record the document's previous numbering scheme; i.e., STCL-GEN-002 Rev 06. If no previous number, record **None**.

8.2.2.3 Record the Change Control Request number in the **Change Number** field.

**NOTE:** If there is no CCR, record **None** in the **Change Number** field.


## 8.2.3 Main File

8.2.3.1 Click on the **Add File** icon () to attach the main file. The **Upload File** window opens.

8.2.3.2 Click the **Browse** button and select file.

8.2.3.3 Click the **Upload File** button to attach the file to the InfoCard. The file name will display in the **File Name** field.

## 8.2.4 Standards

8.2.4.1 If needed, click on the **Add Standards** icon () to add any Standards (an easy way of cross-referencing an InfoCard or including FDA regulations).

**NOTE:** If no other tabs will be completed, click **SAVE**.

## 8.2.5 Date Information

8.2.5.1 The **Created** field will auto-populate once the InfoCard is saved.

## 8.2.6 Controlled Copies

8.2.6.1 Click on the **Copies** icon () to add any Controlled Copies (associated with the InfoCard).

## 8.2.7 Custom Fields

**NOTE:** This is a **required field**. An error message will display if the field is not completed when **SAVE** is clicked.

8.2.7.1 Click on the **\*Custom Fields** Tab.

8.2.7.2 From the **Value** drop-down list, make a selection.

8.2.7.3 Click **SAVE**.

## 8.2.8 Attachments & Links

**NOTE:** This section is used to maintain pertinent files/information related to the document.

8.2.8.1 Click on the **Attachment** icon () to attach the file.

8.2.8.2 Click **Choose Files**.

8.2.8.3 Select file.

8.2.8.4 Click the **Upload** button to attach the file to the InfoCard. The file name will display in the **File Name** field.

8.2.8.5 Click **SAVE**.

## 8.3 Create Packet Task

8.3.1 On the Document InfoCard, click the drop-down menu on the **SIGN OFF** button and click on **New Packet Task**. The **Packet Types** window opens.

8.3.2 Select *Default* under Standard Packet; click Continue.

8.3.3 The **Add Packet Task** screen displays.

8.3.3.1 Complete **Task Name**.

8.3.3.2 The **Instructions** are programmed in the InfoCard Type setting, but additional information can be included.

8.3.3.3 In the **Workflow Information** section of the **Add Packet Task**, select the appropriate Workflow for the task from the **Selected Workflow** drop-down menu.

8.3.3.4 Click the **Launch Task** button.

**NOTE:** If you click the **SAVE** button, the **Packet Task** will be listed in the **Packets** section in the **Start Task** window. (Clicking the **Launch Task** button “jumps” this step. Refer to Section 8.5.)

8.3.3.5 The **Collaborate Packet Actions** screen displays. It defaults to **Native**. Click **Continue**.

8.3.3.6 Search **Pending Tasks** to locate **Task Name**.

8.3.3.6.1 **Modify Step** (👤) accordingly.

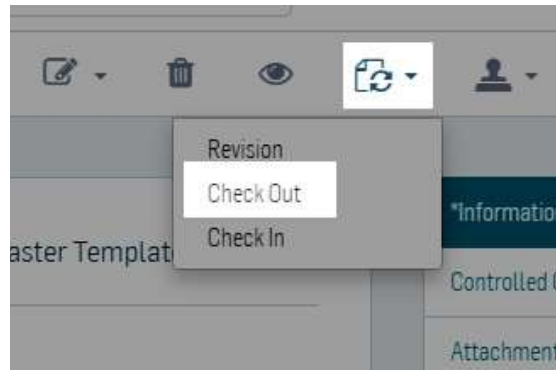
## 8.4 Revising an Existing Document in MasterControl

### 8.4.1 Check Out InfoCard

**NOTE:** MasterControl maintains strict revision control rules. The only way to make changes to an InfoCard and its documents while maintaining a revision history is to check it out and check the InfoCard back into the Vault. Once a file is checked back in, MasterControl makes a new revision of the document and adds it to the list of InfoCards. You can only check out a document from a **RELEASE** vault. **Checking Out** an InfoCard is the only way you can make a change to an InfoCard and its document and maintain a revision history.

8.4.1.1 Locate and load the InfoCard to be checked out.

8.4.1.2 Click the **Check Out** option.



8.4.1.3 In the **Checkout Information** screen, provide the **Change Control Request** number and a brief comment in the **Comments** field.

8.4.1.4 Click the Check Out option.

8.4.1.5 In the Save As window, navigate to the location you want to save the file.

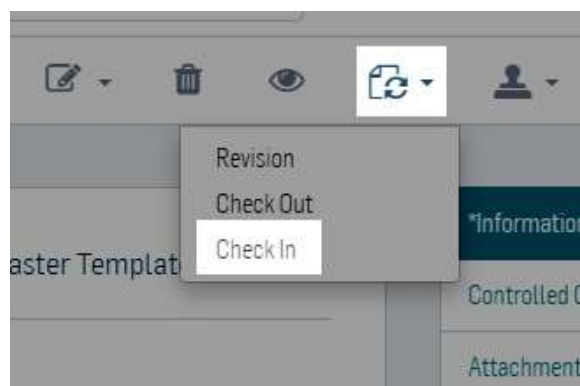
8.4.1.6 Click **Save** or **Cancel**. Clicking **Save** loads the document to the InfoCard; clicking **Cancel** redirects you to the Document InfoCard.

### 8.4.2 Check In InfoCard

**NOTE:** To check in an InfoCard to a vault, you must first have the appropriate Rights to check it out (Check-In InfoCard rights).

8.4.2.1 Load the InfoCard that requires check in.

8.4.2.2 Click the **Check In** option.



- 8.4.2.3 Select the InfoCard to check in by clicking the radio button of the desired **InfoCard Number**.

**NOTE:** To check in an InfoCard that you have **not** made changes to select the **Check In Without Revisions** check box; then click **Check In**. This action unlocks the InfoCard.

**NOTE:** The InfoCard Revision number is incremented by one (1) from the previous revision.

- 8.4.2.4 Click the **Add File** icon (➕). If you elected to use the file from the previous InfoCard, click the **Edit** icon (✎) to attach a new file.
- 8.4.2.5 Click the **Browse** button on the **Add InfoCard Document File** to locate the file.
- 8.4.2.6 Click the **Load File** button.
- 8.4.2.7 Click the **Open** button, and then click the **Load File** button. The Load File window closes and the **Edit InfoCard** page appears.
- 8.4.2.8 The file loads; click the **SAVE** button.

## 8.5 Launch a Packet for a New or Revised Document

- 8.5.1 Prepare InfoCard.
- 8.5.2 Click Sign Off > new Packet Task



- 8.5.3 Select the packet type and click Continue.
- 8.5.4 On the Create Task page, complete the required fields then click **LAUNCH**.

8.5.5 In the Collaboration Packet Actions window, select the appropriate options for each step.

8.5.6 Click **Continue**.

## 8.6 Approving/Releasing a Document InfoCard

8.6.1 Refer to COMM-PAS-026 JA1 *Approving/Releasing a Document InfoCard and Creating a Course InfoCard* and follow the step-by-step guides for set date and releasing a Document InfoCard.

## 8.7 PDF Publishing the Approved Document

8.7.1 Click the **Publishing Queue** item from the **PDF Publishing** section in the Portal menu.

**NOTE:** Do not publish unreleased HTML Form InfoCards. Data changes on a draft Form InfoCard do not trigger a republish.



8.7.2 Click Select InfoCard(s) to find and add an InfoCard to the Conversions queue.



8.7.3 Click an InfoCard Number to view the InfoCard in the queue. To open several InfoCards simultaneously, select InfoCards from the Conversions queue and click View InfoCard(s).



8.7.4 Click Remove to remove an individual InfoCard from the publishing queue.





- 8.7.5 Click Force Processing to force a single item in the queue to the next processing step.



- 8.7.6 Click Start to force the default number of items in the queue—designated in the Threshold field of the Configuration Parameters page to the next processing step.



**NOTE:** Run All is not recommended as it requires a large number of resources.

- 8.7.7 Click Upload PDF to upload the PDF file and add it to the Modifications queue for any necessary modifications

## 8.8 Issuing Documents

- 8.8.1 Documents are issued electronically via the system upon the document effective date.

## 8.9 Archiving/Expiring Document InfoCards

- 8.9.1 Document InfoCards are archived per their set Lifecycle.
- 8.9.2 Document InfoCards requested via a Change Control Request to be permanently removed from the system are assigned an Expiration Date and the Course InfoCard is moved to the Course Archive vault; e.g., document number change; document no longer used.

## 9 RELATED DOCUMENTS/FORMS

- 9.1 COMM-PAS-004 Change Control
- 9.2 COMM-PAS-022 Configuration of Numbering Series Patterns in MasterControl
- 9.3 COMM-PAS-026 JA1 Approving/Releasing a Document InfoCard and Creating a Course InfoCard

## 10 REFERENCES

- 10.1 MasterControl System Administration Online Help

## 11 REVISION HISTORY

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

**Signature Manifest****Document Number:** COMM-PAS-026**Revision:** 01**Title:** Document Control Procedures for MasterControl**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

**Medical Director**

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