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

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MasterControl Process System Configuration and Administration

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COMM-PAS-024
MasterControl Process System Configuration and Administration

1 PURPOSE

1.1   This procedure describes the process required to configure and administer the MasterControl (MC) Process for the purpose of automating form-based processes.

2 INTRODUCTION

2.1   MasterControl Process automates, streamlines, and effectively manages form-based processes to help ensure compliance with FDA regulations with electronic records. Additionally, MC Process enables users to control the data input, the processing, and the reporting (output) of data.

3 SCOPE AND RESPONSIBILITIES

3.1   This procedure covers MasterControl Process configuration, HTML to support e-forms design, system fields, form template creation, and route construction.

3.2   This procedure applies to the System Administrator and the SubAdmin.

3.3   The System Administrator is responsible for the configuration, administration, and control of the MasterControl Process software.

3.3.1   In the absence of the SysAdmin, this responsibility can be delegated to the Sub-Administrator.

4 DEFINITIONS/ACRONYMS

4.1   21 CFR Part 11 – Electronic Records; Electronic Signatures

4.2   MC – MasterControl

4.3   HTML – Hypertext Markup Language

4.4   Form Template– An electronic file that is equivalent to a master copy in a paper-based system.

4.5   eSig – Abbreviation for electronic signature.

4.6   SysAdmin – System Administrator

5 MATERIALS

5.1   NA

6 EQUIPMENT

6.1   Computer to access 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   NA

8   PROCEDURE

8.1   Creating a New Form Template InfoCard

NOTE: MasterControl Process leverages HTML technology to support e-forms design. The general steps for creating a Form Template InfoCard are the same as for creating a regular InfoCard. Form Template InfoCards <u>must</u> have an HTML form uploaded as the main file.

    8.1.1   PROCESS > Process Configuration > Template InfoCards
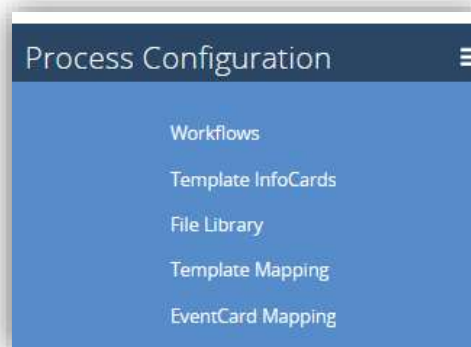
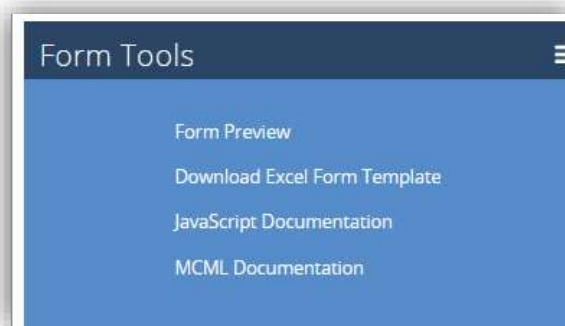   8.1.1.1   Click the New icon.

        8.1.1.2   Select the desired **InfoCard Type**; click **Continue**.

        8.1.1.3   Add information to the new Form Template InfoCard.

        8.1.1.4   Save.

    8.1.2   PROCESS > Forms Tool > Download Excel Form Template

        8.1.2.1   Create the form using the Excel worksheet.

            8.1.2.1.1   HTML forms are created through the Process module.

            8.1.2.1.2   Data entered in an HTML e-form will appear as output in a report.

8.1.2.2   Use Form Preview to view the creation of the form.

8.1.2.3   Save file using extension .xlsm

NOTE: .xlsm = macro-enabled Excel file

8.1.3   Under Main File, browse for the desired HTML file, and load it as the main file.

8.1.4   Click the **Form Fields** tab. MC automatically detects and lists fields from the form.

NOTE: If any of the reserved MC system field names were used, the fields will be disabled (grayed out) on the **Form Fields** tab. The **data type** and **exclude options** for these fields are pre-set. MC will not allow a user to save the form without first clicking on the **Form Field tab**. An error message will appear if this tab is not viewed before saving.

8.1.5   Approve the Form Template InfoCard using **Quick Approve** (eSig required).

8.1.6   Click Save.

8.2   Creating New Form Route

8.2.1   Select Workflows
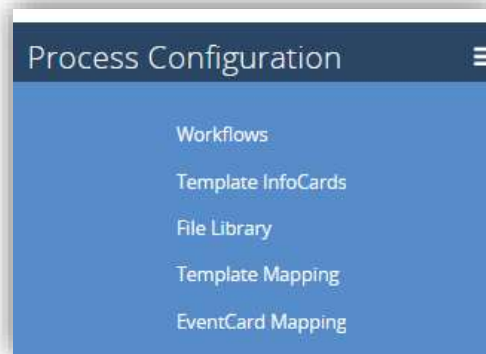
8.2.2   Click **New**.

8.2.3   Enter Workflow Properties; click **Done**.

8.2.4   Create a Workflow using graphical icons in the Workflow Builder.

8.2.5   Assigned Roles – Choose one or more roles that will have access to the

8.2.6   Click the **Save** button.

8.2.7   Statuses include the following:

8.2.7.1   Data Complete – Signifies that data entry is complete and that the form should move on to the next step.

8.2.7.2   Data Approval – Signifies that data is approved and that the form should move on to the next step.

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8.2.7.3   Data Rejection – Signifies that data is not approved. Signing off on a form task with this status will cause the form to be returned to the previous Data Entry step.

8.2.7.4   Work in Process – Saves the data currently entered into the form but does not send the form on to the next step.

8.2.7.5   Final Approval – Signifies that all data is approved and that the form should bypass all future steps. The form will immediately be moved from the draft vault to the release vault.

8.2.7.6   Final Rejection – Signifies that the form should be immediately moved to the designated Abort Vault.

8.2.7.7   Revisit – Allows the user to set a time interval (e.g., 7 days). During that time, the task is removed from the My Tasks area. Once the time has elapsed, the task will reappear in the My Task area.

8.2.7.8   Notify – Users on a Notify step will receive an email update of form progress.

8.2.8   Highlight the Page and click the button that will correspond with the desired page action; then click OK.

8.2.8.1   Make Editable – Pages can be viewed and edited.

8.2.8.2   Make Read Only – Pages can be viewed but not edited.

8.2.8.3   Hide Page – Pages are hidden and cannot be viewed.

8.2.9   Click **Save** to save the Workflow.

8.3   Make Workflow Available

8.3.1   Click the **Workflow** icon (to enable or disable a workflow)
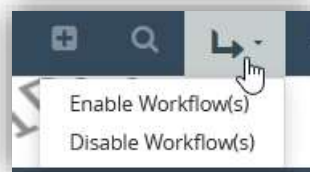
8.3.2   Click **OK**.

9   RELATED DOCUMENTS/FORMS

9.1   COMM-PAS-021 MasterControl Portal & Documents System Configuration and Administration

10   REFERENCES

10.1   MasterControl System Administration Online Help

10.2   21 CFR Part 11 – Electronic Records; Electronic Signatures

11 REVISION HISTORY

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01	M. Christen	• New document

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