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**DOCUMENT TITLE:**
MasterControl User Procedures - Documents

**DOCUMENT NOTES:**
Updates for MC v2021.3.

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COMM-QA-060
MASTERCONTROL USER PROCEDURES – DOCUMENTS

1 PURPOSE
1.1 This procedure provides the details for using and navigating MasterControl Documents.

2 INTRODUCTION
2.1 The document management system, MasterControl, will provide the ability to create, route, and control all document control tasks.

3 SCOPE AND RESPONSIBILITIES
3.1 This procedure covers the operational (systematic) instructions on how to use MasterControl as a Creator/Revisor user.
3.2 It is the responsibility of all employees using MasterControl to follow and apply these procedures as outlined.

4 DEFINITIONS/ACRONYMS
4.1 21 CFR 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 Change Control Request (CCR) – A vehicle used in the process of approving and documenting changes to controlled documents, processes, equipment, operations, and design change(s) to ensure compliance with applicable regulatory requirements.
4.3 Collaboration – Collaboration is a MasterControl application that allows a user to work jointly with other users on a document in an electronic route.
4.4 Creator/Revisor Users – Users that have the ability to view, create, edit, approve, and reject documents.
4.5 DCO – Document Control Operations
4.6 DUO – A service used for multi-factor authentication (MFA).
4.7 Esig – Abbreviation for electronic signature that is considered as a legally acceptable and functionally binding equivalent of a paper-based signature.
4.8 Fields – Space allocated for specific information or a certain piece of information.
4.9 HTML (Hypertext Markup Language) – A standard language used to create online eForms.
4.10 Hyperlink – An electronic link providing direct access from one distinctively marked place in a document to another in the same or a different document.
4.11 InfoCard – The InfoCard controls access to documents as well as the functions available to each user. InfoCards are the core of MC.
4.12 MasterControl (MC) Portal/Documents – A configurable off-the-shelf software system used for the automation and control of document approval, change control, distribution processes, and employee qualification (training).

4.13 MasterControl Portal – Provides the gateway and access to all major functions needed to set up and maintain the MasterControl applications.

4.14 MFA (Multi-factor Authentication) – This action provides an additional layer of security when logging in to a Duke system. A user is required to enter a password and also authenticate by using a second factor, typically an iPhone.

4.15 Native application – Referring to the original system or application used to create a document; e.g., Microsoft Word.


4.17 Okta – An enterprise-grade, identity management service, built for the Cloud.

4.18 Packet – The vehicle that carries an object (a task) through an approval cycle.

4.19 Route – A route is the workflow component of a task. A route is composed of a series of steps, which include a predefined sequence of users who must act upon the task contents.

4.20 SOP – Standard Operating Procedure

4.21 System Administrator – The person or position responsible for the administration, configuration, and control of the MasterControl software.

4.22 Task – An assigned piece of work to be completed within a certain time.

4.23 Tiles and Hubs – MasterControl’s design of their user interface (UI).

4.24 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are of three (3) common types: Draft, Release, Archive.

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 Components of MasterControl

8.1.1 User Interface (UI)

8.1.1.1 This upgraded version of MasterControl maintains the same Sign In screen as the previous version.

8.1.1.2 To change the color theme of the interface, click the drop-down menu next to your Username in the upper right corner; then select your preference.

8.1.1.2.1 Color Theme changed.
8.1.2 Hubs and Tiles

As a result of MasterControl's all-inclusive approach to user experience (UX), users do not have to jump to a different module to perform related tasks. The Hubs replace the landing pages formally associated with each MasterControl module. The Hubs contain tiles with critical information and tasks, which allow users to easily navigate between pages or perform additional tasks. This creates a truly connected workflow that aligns more directly to how users perform their jobs.
8.2 System Login to MasterControl Portal Home Page

8.2.1 Click on your browser (Firefox or Chrome or Chrome Incognito).

8.2.2 Type in the following URL address:
https://duke.mastercontrol.com/duke/login

**NOTE:** Bookmark this URL site for easy access.

The MasterControl Login Screen displays.

8.2.3 In the User ID field, enter your Duke NetID followed by @duke.edu

**NOTE:** Example: bj42@duke.edu

8.2.4 Click ENTER or click the TAB key.
8.2.5 The **PASSWORD** field is removed.

8.2.6 Click the **Sign In** button.

![Sign in to your account](image1)

8.2.7 Clicking the Sign In button redirects you to the **Duke Log In** screen.

![Duke Log In](image2)

8.2.8 Enter **your** Duke NetID credentials, along with a **Duo** authentication 6-digit number for your **MFA**.
Example:

NetID
Current students, faculty, staff, sponsored guests

8.2.9 Click Log In.
8.2.10 Your MasterControl home portal page displays.

8.3 My MasterControl

8.3.1 **My MasterControl** (item #1, Section 8.1.2) provides ready access to commonly accessed areas of the system.

8.1 My Tasks

8.1.1 MasterControl has replaced the old “In Box” on your desk with a handy repository for all the tasks that require your attention. This is the **My Tasks** page (item #2, Section 8.1.2), where you open the document you need to complete, access the collaboration workspace for documents that need your revision, or sign off on any task requiring your approval. **My Tasks** provides easy access to all your pending tasks.
8.2 My Settings

8.2.1 When you are logged in to MasterControl Portal, the main application header contains a number of items to facilitate use of the system. Clicking on the MasterControl icon (item #1, Section 8.1.2) in the top-left will return the user to the MasterControl Portal Home Page from any other page.

8.2.2 The Log Out link located in the top-right of the header will log you out of MasterControl Portal.

NOTE: Be sure to click on either Log Out to release your session for another user.

8.3 Change Passwords

8.3.1 Change your esig password if the system prompts you to do so, if you want to update it, or if you forget your current esig password.

8.3.2 Click the User Name drop-down menu; select Change Passwords.
8.3.3 The Change Passwords screen will display.

8.3.4 The **eSignature** tab will display.

8.3.5 Satisfy the specific requirements for the esig password.

8.3.5.1 Minimum esig characters = 5

8.3.5.2 Forced alphanumeric; i.e., at least one (1) number and at least one (1) letter.

8.3.5.3 Expires after 90 days and must be reset.

8.3.5.4 Lockout occurs after five (5) attempts.
NOTE: Duke OIT implemented a password policy that eliminates the need to change NetID passwords, unless compromised. This updated password policy removes password expiration and will no longer require Duke users and sponsored guests to regularly update login passwords associated with their Duke NetID.

8.3.6 Click Save.

8.3.7 The Change Reason window will display for you to include a brief reason for the change; i.e., updated my esig.

8.3.8 Click Save.

8.4 Out of Office

8.4.1 Users can set their own account status to Out of Office. When a user’s out of office starts, the feature forwards selected approval, document, and forms tasks to a designated alternate.

8.4.1.1 Generally, Out of Office is used if a user is scheduled to be out for an extended period of time.

NOTE: Training tasks cannot be redirected.

8.4.1.2 In the My Settings tile (item #8, Section 8.1.2), check Out of Office.

8.4.1.3 OR click Quick Navigation.

8.4.1.4 Type My Settings to locate and select the Out of Office option.
8.4.1.5 Click the open selector to search for and select an alternate.

**NOTE:** Ensure to have the alternate’s permission prior to setting the OOO.

8.4.1.6 Choose the **Start Date** and **End Date** by using the calendar selector for future occurrences, or click the **Today’s Date** option to set your Out of Office for the current day. The **End Date** is still required in the event of an open-ended absence.

8.4.1.7 Click a radio button to determine whether or not to include in-process tasks.

8.4.1.8 By default, all eligible tasks are directed to the Alternate. To select specific tasks, click **Selected Tasks** and move the tasks to **Selected Tasks**.

8.4.1.9 To modify or cancel a scheduled Out of Office event, click **Modify** or **Cancel** for the specific event.
8.4.1.10 Click Save.

8.5 End Your Out of Office Status

8.5.1 When you log in to MasterControl for the first time after changing your status to Out of Office, you are prompted to change your status to In Office.

8.5.2 When the reminder appears, click OK.

8.5.3 To end the Out of Office status and return to In Office, click the X under the ACTIONS column.

8.5.4 Click OK to delete the OOO setting.

8.6 My Links

8.6.1 My Links is a links section that provides quick access to different landing pages or actions within the MasterControl system. You can access, create, and manage private links that all users can add to their home pages; however, users may only access those links for which they have corresponding rights.

8.6.1.1 For help on creating Links, you can visit the Help (item #6, Section 8.1.2) or contact DCO.

8.7 Start Task

8.7.1 When new eForms need to be filled out, the eForms are sent on specific Data Entry Workflows in HTML format from the Start Task tile (item #3, Section 8.1.2) on the Home Portal page.
8.8 Tracking

8.8.1 All tasks are tracked during the approval process and retained after they have completed their respective Workflows. From the My MasterControl Tracking page (item #10, Section 8.1.2), you can search for a specific task, and then view the status or history details of the task, along with its file or form. Task details show all the steps that a task has completed, steps yet to be completed (if in-process), and comments made by users along the Workflow.

8.9 My Recent

8.9.1 The My Recent menu (item #5, Section 8.1.2) allows quick retrieval of any of the last 15 InfoCards with which you have worked with or viewed. Mouse over the menu and select the desired InfoCard. The system will navigate directly to it. The most recent InfoCard appears at the top of the list.

8.10 Explorer

8.10.1 Use Explorer (item #9, Section 8.1.2) to view your Organizers as a list or in a tile view, or sort and filter your Organizers for an improved search experience. The Explorer page provides visual access to organized InfoCards in an HTML view. You can view the contents of an organizer in this view, but cannot edit them. There is an Explorer tile located on MY MASTERCONTROL, PORTAL, and DOCUMENTS modules.

8.10.1.1 Select the Organizer to view by clicking.

8.10.1.2 A list of documents contained in the subfolder populates. Click the document to view.

8.11 My Training Folder

8.11.1 My Training Folder (item #4, Section 8.1.2) is a listing of every training task that has ever crossed your path. Anything you want to know about your training record can be found here, from task statuses, past and future due dates, completion dates, when retraining will be required, and who verified your training.
8.11.2 Refer to COMM-QA-062, MasterControl User Procedures – Training, for detailed MC Training information.

8.12 Analytics

8.12.1 The Analytics menu (item #7, Section 8.1.2) allows you to access reports to which you have rights in MasterControl Analytics. From this menu item in the My MasterControl section, you can view MasterControl Analytics reports for all installed applications. Each application in the menu also has a “Reports” menu item, which allows you to access reports for that application.

8.13 Search MasterControl

8.13.1 The Search function offers three search methods: Simple, Basic, and Advanced, which behave similarly in the Portal and Toolbar searches. Search results display only InfoCards that belong to vaults for which you have rights.

NOTE: Search fields in MasterControl have a 50-character limit.

8.13.2 Portal Search

8.13.2.1 Locate the Portal Search toolbar at the top of the page from anywhere in the MasterControl interface. When you search using Portal Search, MasterControl scans the entire portal for defined values and displays results in folders according to module for easier navigation of application-wide searches.

8.13.3 Toolbar Search

8.13.3.1 Locate the Toolbar Search from the InfoCard list page toolbar. The Toolbar Search returns only results from the InfoCard list page from which you initiate the search. Results are displayed in a sortable InfoCard list. Click the checkbox for one or more of the InfoCards to perform actions such as check-in, view, and create or view copies.
8.13.4 Simple Search

8.13.4.1 Simple Search displays a single field for you to specify your search criterion. The system compares the values you type in the search field against all searchable fields.

8.13.4.2 Select either the Portal or the Toolbar Search option.

8.13.4.3 Click Simple.

8.13.4.4 In the Search for field, type the words for which you want to search.
8.13.4.5 Click Submit Search and view the search results.

8.13.5 Basic Search

8.13.5.1 Use Basic Search's Query by Example feature to tailor your search and compare the values you type in the search fields against all searchable fields. You can use an asterisk (*) as a wildcard before a search term to look for results that contain the term or include an underscore (_) as a single-character wildcard for any character that contains letters and numbers.

**NOTE:** If you include an underscore in your search, wrap the underscore in brackets ( [_ ] ) so that the search recognizes the character as itself.

8.13.6 Select either the Portal or the Search option.

8.13.6.1 Click Basic.

8.13.6.1.1 In one or multiple fields, type your search criteria.
NOTE: To remove all field entries, click Clear.

8.13.6.1.2 Click Submit Search.

8.13.7 Advanced Search

8.13.7.1 Use Advanced Search to narrow search results to specific values in particular fields. You can also select a field, an operator, and a field value for the search, as well as add more search fields.

8.13.7.2 When adding additional fields, if you want results to include information you type in both specified fields, use the "and" logic. If you want the results to include information you type in either one field or the other, but not both, use the "or" logic.

8.13.7.3 When populating the Value field, you can use an underscore ( _) as a single-character wildcard for any character, including letters and numbers. If you search for a term that includes an underscore, wrap the underscore in brackets ([_]) so the search recognizes the character as itself.

8.13.8 Select either the Portal or the Toolbar Search option.

8.13.8.1 Click Advanced.
8.13.8.1.1 Click the Field drop-down and select a field from which to search.

**NOTE:** The Advanced Search field options for each InfoCard list may vary based upon the fields MasterControl has built into each feature.

8.13.8.1.2 Select an Operator from the drop-down list:
- Contains
- Does Not Contain
- Ends With
- Equals
- Starts With
- Is Null
- Is Not Null

8.13.8.1.3 Type the search value. For date fields, click Calendar View to choose a specific date, or click Today's Date to set the value to the current day.

8.13.8.1.4 To add an additional search field, click New Row, indicated by a plus sign, and select the and/or logic from the drop-down.

**NOTE:** To delete a search field, click Delete Row.

8.13.8.1.5 Click **Submit** Search.

8.13.9 Full Text Search (FTS)

**NOTE:** This option conducts a search for the content in the main file attached to the InfoCard.

**NOTE:** It does not recognize headers or footers.

8.13.9.1 To perform a FTS, use the **Advanced** search method as described in Section 8.13.7.

8.13.9.1.1 Select the Full Text Search option from the drop-down list.
8.14 MasterControl Icons

8.14.1 Hovering or pausing over an icon reveals the name/function of that particular option.

8.14.2 An **Icon Directory** can be found in the **HELP** (item #6, Section 8.1.2) tile of any module.
8.15 Document InfoCard

**NOTE:** InfoCards are the core of MC. The InfoCard controls access to documents as well as the functions available to each user. This section describes the tabs you will see on a Document InfoCard.
8.16 InfoCard Page Tabs

8.16.1 InfoCard information is stored in tabs within each InfoCard page. An InfoCard may contain any or all of the following tabs (depending on application).

8.16.1.1 Information — includes general data about the InfoCard including Version, Main File, Date, and Standards

8.16.1.2 Training — displays a list of all training tasks to which the Document InfoCard has been linked.

8.16.1.3 Controlled Copies — contains copy information such as Location

8.16.1.4 Attachments & Links — contains information about the attached document(s) and other applicable links.

8.16.1.5 Custom Fields — includes information about the InfoCard’s Custom fields.

8.16.1.6 History — contains information about the history of the InfoCard including Vault, Review Date, Release Date, Effective Date, Expiration Date, and Actions.

8.16.1.7 Status — displays the InfoCard’s status information, including Locked, Workflow.

8.16.1.8 Versions — contains information about the previous versions of the InfoCard.

8.17 Creating and Revising Documents

NOTE: COMM-QA-057, Procedure Development, and COMM-QA-057 JA1, Procedure Development SOP Template JA1, define the steps required to develop/create a new procedure or document. A specific numbering scheme for the new document will be assigned when the document is entered into MC.

8.18 Creating New Document

8.18.1 Document Creator

8.18.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 FRM1 Change Control Request (Effectiveness Check); or COMM-QA-019 FRM2 Change Control Request (No Effectiveness Check) for change controls for the CCBB or GMP programs.

8.18.1.2 For the ABMT, PBMT, and STCL programs, use COMM-PAS-004, Change Control.

8.18.1.3 Create the new document by following the COMM-QA-057 Procedure Development and COMM-QA-057 JA1 Procedure Development SOP Template JA1.

8.18.1.4 Email the new document with additional instructions, if needed, to DCO for entry into MasterControl.
8.18.1.5 Upon approval of the CCR, DCO will create a Document InfoCard for the new document and launch the document packet for collaboration, review, and/or approval in MC.

8.19 Revising Existing Document

8.19.1 Document Initiator

8.19.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 FRM1 Change Control Request (Effectiveness Check) or COMM-QA-019 FRM2 Change Control Request (No Effectiveness Check) for change controls for the CCBB or GMP programs.

8.19.1.2 For the ABMT, PBMT, and STCL programs, use COMM-PAS-004, Change Control.


8.19.1.4 Upon approval of the CCR, DCO will follow the instructions of the CCR and enter the file (or attach a new one if provided by the Author) into the system. The file will be launched for collaboration, review and/or approval in MC.

8.20 Collaboration

**NOTE:** MasterControl Collaboration is used to receive feedback on document content from more than one user, allow users to sign off on documents, view comments from other users, and add comments for others to see.

**NOTE:** When a collaboration leader adds a user to a task, a link to the task displays in My Tasks and directs the user to the Collaboration Workspace to complete the task and perform other collaboration functions.

**REMINDER:** Inclusion in the collaboration process affords the collaborator the opportunity for input to the content of a document. The role of a collaborator is to review the assigned document and provide timely feedback to the author based on the collaborator’s unique expertise or perspective. To avoid duplication of work and/or implementation of a flawed document, feedback from the collaborator must be received before collaboration on the document is ended by the author. Once collaboration has closed, further change(s) must be incorporated in the next revision of the document. When this happens, not only must previous efforts be duplicated, it can result in a significant delay in implementation of the change(s).

**NOTE:** This section details the steps required to collaborate on a task. Specific instructions for additional functions for a **Collaboration Leader** are detailed in Section 8.21-8.31. **Collaborator** information is detailed in Section 8.30.2.
8.21  Collaboration Workspace

8.21.1  Click My MasterControl → My Tasks.

8.21.2  Click the Collaborate icon for the task you want to open the Collaboration Workspace.

8.22  Manage Task Details

8.22.1  Manage the due date, instructions, task attachments from the Task Details tab.

8.22.1.1  In the Collaboration Workspace, click Task Details.

8.23  Set the Collaboration Status (optional)

8.23.1  Select an option to inform other collaborators of the collaboration’s current status.
8.23.2 In the Select Collaboration Status pop-up, click the drop-down and select an option.

8.23.2.1 Click SAVE.

8.24 Set a Collaboration Due Date (optional)

8.24.1 Set a due date for collaboration users during the process of a collaboration. When a collaboration task has a set due date, the date appears in the My Tasks page. This task displays in red on the day of the due date.

8.24.2 In the Collaboration Workspace, click Due Date.

8.24.3 In the Enter a Date field, click Calendar View and select a date or click Today’s Date.
8.24.3.1 If options were selected, the Status and Due Date would appear like this:

![Status: Waiting for Responses
Due Date: 05 Apr 2021]

8.25 View and Edit a Collaboration

**NOTE:** Use the Collaboration Workspace to view or edit an InfoCard's main file. You can also view previous redlines made to the main file.

When you check files out for redlining, MasterControl's Collaboration feature locks the InfoCard so other users cannot redline the same document until the file is either uploaded or unlocked. Collaboration Leaders can unlock any file, but other users can only unlock files they have locked.

8.25.1 In the Collaboration Workspace, click View File.

![Actions](image)

**NOTE:** When engaging this View File option, the file CANNOT be edited.

![This file should only be viewed. Any changes may be lost.]

8.25.2 Select the **Edit File** icon under the **Collaboration Actions** column to open the document.

**Collaboration Workspace NOT Locked**

**Collaboration Workspace Available for Editing**

**Collaboration Workspace Locked**

8.25.3 Click OK to open the file, turn on Track Changes to edit.

8.25.4 Click **SAVE** and **CLOSE** the newly redlined document.
8.25.5 Click the **Refresh** icon to **UPLOAD** your changes to the Collaboration Workspace.

8.25.5.1 Additionally, you can use the **UPLOAD CHANGES** icon to upload your document.

8.25.5.1.1 Click Browse and locate the file, then click Open.

8.25.5.2 Click Load File to **UPLOAD** the redlined document.

8.25.6 After upload, if desired, view the changes by clicking on the **View Changes** icon under the Collaboration Actions column.

8.26 Manage a Collaboration Attachment

8.26.1 Add, remove, and download collaboration attachments in the Collaboration Workspace.
8.26.2 Complete one of the following actions, as needed.
   8.26.2.1 Add
   8.26.2.2 Delete
   8.26.2.3 Download

8.26.3 Click Close.

8.27 Manage Collaboration Comments

   NOTE: View, add, or delete comments to collaborators in the Collaboration Workspace.

   NOTE: Users can only delete their own comments. Comments added by other users are visible to all collaborators.

   NOTE: Comments appear in the Comments section with your name and time/date stamped.
8.27.1 The **Comments** section allows users to exchange ideas and comment outside the context of a document. Collaborators can add comments, delete own comments, view other user’s comments, and e-mail users.

8.27.2 Comments can either be added through the **Comments** section, or by entering them when signing off on a collaboration task. Comments made during sign-off are identified in the Comments section by a “Sign-Off Comments” subject.

8.27.3 To add a comment:

8.27.3.1 Tap **Add Comment** to expand the **Comments** field.

8.27.3.2 Type your message in the **Comments** field.

8.27.3.3 Click Add Comment.

8.27.3.4 If you want to delete a comment, click **Delete Comment** next to any comment you previously added.

8.28 **Manage Collaboration Members**

**NOTE:** Manage collaboration members from the Members section of the Collaboration Workspace, even if the task already launched.

8.28.1 Click **Show** or **Hide** the Collaboration Members.

8.28.2 The Collaboration member names display in the following way:
8.28.3 You can e-mail any user in the collaboration by clicking the **E-mail** icon. Clicking the icon next to a user’s name will e-mail that user. Clicking the icon at the top of the **Members** section will e-mail all the users in the list.

8.29 **Modify Step**

**NOTE:** All Collaboration Leaders are automatically granted the right to add or remove users from specific steps. This is called Modify Step. A Modify Step icon will display next to tasks in your Pending Task List to which you are the Collaboration Leader.

**NOTE:** During the course of a route, Collaboration Leaders may modify any step by adding or removing users.

**NOTE:** If the user or users you add to a step are **out of office**, you will receive an alert stating that the task will be assigned to their alternate.

8.29.1 Click the **Modify Step** icon (📧) located in the **ACTIONS** column of the Pending Tasks page or in the **MEMBERS** section of the Collaboration Workspace.
8.29.2 To add a user(s), click the **GREEN + button**, type in user to add, click **GO**, and select correct user; then click **ADD**.
8.29.3 To remove a user, click on the user to be removed. Click on the **RED – button** to remove the user.
8.29.4 Click SAVE.

8.29.5 Use the up and down arrows to promote or demote a user to a different role; i.e., from the Collaboration Leader frame to Collaborators frame and vice versa.
8.29.1 Click Save.

8.30 Signing Off on Collaboration

8.30.1 After you complete your portion of the collaboration, choose one of the following sign-off options:

8.30.2 When your portion of the collaboration is complete (through adding redlines, comments, etc.), you are ready to sign off on the task. **COLLABORATORS** have two (2) options when signing off on a collaboration: Complete or Complete and Quit.

8.30.3 Selecting Complete allows the user to sign off on the collaboration. However, the user will receive notification each time a new redline has been uploaded, and the collaboration will reappear in the user’s task list, allowing further input.

8.30.4 Selecting Complete and Quit allows the user to sign off on the collaboration. It also permanently removes the task from their task list (not to be seen again).

8.30.5 To sign off on a collaboration task, complete the following steps:

8.30.5.1 Upload the outstanding redline to the task.

8.30.5.2 Click the Sign Off button in the toolbar.
8.30.5.3 You may elect to enter a comment in the Comments field, but it is not required.

8.30.5.4 Type your esig in the appropriate field.

8.30.5.5 Select either Complete or Complete and Quit from the Status field.

8.30.5.6 Click the Save button.

8.31 Collaboration Leader

**NOTE:** A **COLLABORATION LEADER** (usually the Author of the document) can perform additional tasks, e.g., modifying collaborators, replacing InfoCard main file with other files or the latest redline, ending or aborting collaboration. When collaborations are complete, the Collaboration Leader will want to ensure the most accurate file is included in the InfoCard. MC Collaboration gives the leaders the right to replace the main file of InfoCards in the tasks. Throughout a collaboration, leaders have the option to abort the collaboration step, ending the route and returning the task to an unlaunched state.

**NOTE:** Only **COLLABORATION LEADERS** can abort or end a collaboration, but they do not have the option to quit. All other collaboration members can only sign off with Complete or Complete and Quit. If there is more than one leader on a collaboration step, all users except the last leader to sign off have the Complete option. Leaders with this option can make additional changes and sign off. The collaboration task then resends for feedback. The last leader to sign off must select the **End Collaboration** option to end the step.

**NOTE:** The **COLLABORATION LEADER** **MUST** perform the “Update InfoCard Main File” before signing off.

8.31.1 Replacing InfoCard Files

8.31.1.1 The Collaboration Leader is responsible for replacing the main InfoCard File (Update InfoCard Main File) **before** Ending Collaboration.

8.31.1.2 If this step is NOT completed, a message will appear when you click the Sign Off icon.
8.31.2 Click Update InfoCard Main File Icon

8.31.3 Select **Use Latest Redline** to use the latest redline of an InfoCard file. To add a different file, either type the path and the filename in the **Select File** field or click **Browse** and locate the file.

8.31.4 Click Load File

**NOTE:** If this Replace File operation is not completed, you will lose the redline files, which would require you to restart the Collaboration process.

8.32 Ending/Aborting Collaborations

8.32.1 **End Collaboration** status sends the document on an Approval Route.
NOTE: Once Collaboration has ended, no additional changes can be made unless another user REJECTS the task back to the Collaboration step.

8.32.2 Aborting Collaboration status ends the Route and returns the task to an unlaunched state.

8.33 Print Collaboration Information

8.33.1 Print the information displayed on the Collaboration Workspace tab or Task Details tab

8.33.2 In the Collaboration Workspace, click Print.

8.34 Rejecting a Document

8.34.1 If any user on a route rejects a task, that task is archived and a new task is started in its place with the same document.

8.34.2 A collaboration step is added so the reason the task was rejected can be examined and fixed.

8.34.3 The author, owner, originator, and rejeter of the packet task are included in the collaboration.

8.34.4 After completion of the collaboration step, the packet task can be sent on its original route again. If it is sent on the route, the rights of all users in the collaboration remain the same as they were before the packet task was rejected.

8.34.5 All changes made to the route via Modify Step will be intact.

8.35 Tracking Collaboration Tasks

NOTE: All tasks are tracked during the approval process and retained after they have completed their respective routes. Task details show your tasks and all the steps that a task has completed, steps yet to be completed (in-process ☐), and comments made by users along the route. All in-process tasks show up in Tracking (item #10, Section 8.1.2).
8.36 PDF Files

8.36.1 PDF files are in a distributable format to allow electronic information to be transferred between various types of computers.

8.36.2 MasterControl generates PDF files in “sandwich” the actual document between a cover page and a signature manifest page.

8.36.2.1 The Cover Page maintains the metadata of the document; e.g., document number, revision number, document title, etc.

8.36.2.2 The Signature Manifest page is populated and published on all PDF documents as the last page. Signature Manifest is a FDA 21 CFR Part 11 requirement that allows users to see who has had any action on the document, such as approval, review, rejection, etc.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-057 Procedure Development

9.2 COMM-QA-057 JA1 Procedure Development SOP Template JA1

9.3 COMM-QA-019 Change Control Request (Effectiveness Check) FRM1

9.4 COMM-QA-019 Change Control Request (No Effectiveness Check) FRM2

9.5 COMM-PAS-004 Change Control

9.6 COMM-QA-062 MasterControl User Procedures – Training

10 REFERENCES

10.1 MasterControl System Administration Online Help

10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

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<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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| 09           | B. Jordan | • Updates made to reflect system upgrade to v2021.3 cloud-hosted MasterControl.  
               |         | • Included specifics about Duke OIT security policy for login passwords and changes to esig requirements.  
               |         | • Captured items 1-10 in Section 8.1.2 and incorporated the item number into text thereby removing some images.  
               |         | • Some images updated to match those for v2021.3. |
## Signature Manifest

**Document Number:** COMM-QA-060  
**Title:** MasterControl User Procedures - Documents  
**Effective Date:** 01 Nov 2021  

*All dates and times are in Eastern Time.*

### COMM-QA-060 MasterControl User Procedures - Documents

#### Author

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#### Medical Director

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#### Quality

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#### Document Release

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