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Creating and Collaboration of a Document Infocard in MasterControl

Purpose

This procedure provides instructions for creating and the process of collaboration of a document in MasterControl.

Scope

All personnel trained in performing and implementing any of the activities described in this procedure.

Responsibility

The table below lists the actions and responsible parties for this procedure.

Action	Responsible Party
Review and Approval	Laboratory/Medical Director or designee
Oversight, Maintenance and Training	Quality Assurance
Implementation of the activities described in this procedure	All trained personnel performing any of the tasks in this procedure

Definitions

Approval Route	A document route in which a document is sent for initial and/or final approval. Changes cannot be made to any document on an approval route without being "rejected" first by the approver.
Collaboration Leader	The collaboration leader has the ability to add members to a collaboration task, and has the authority to end or abort the collaboration task at any time. The Collaboration Leader is the only one in a collaboration task who has final say on the document, and who can launch the document on an approval route.
Collaboration Member	A user that is added by a Collaboration Leader for the purposes of making redline changes to a document.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Definitions (continued)

Collaboration Workspace	A place to provide input and changes to the uploaded file of an InfoCard before routing it for approval. In the normal course of collaboration, users will enter the collaboration workspace, copy a file for modification (redlining), modify the document (tracking or redlining the modifications), upload the modified document (redline), add comments if necessary, and then sign off on collaboration. Signing off on collaboration signifies that the user is finished with their modifications or has determined that no modifications are required.
Effective Date	The date entered on an InfoCard that is intended to be the date the related document becomes effective or implemented.
Electronic File	A document file that is created and saved on a user's computer for the purpose of uploading into the MasterControl software application. Electronic files should always be deleted off of the user's computer after proper upload of the document into MasterControl.
Electronic Signature	A unique password associated with a specific user, in place of the traditional written signature.
Infocard	Infocards contain information about a specific document. Examples of this information include: InfoCard #, Title, Author, Owner, Vault, Released Date, Retired Date, Notes, or any other information pertinent to that document. Each document within MasterControl must be associated with an InfoCard in order to be filed, searched and/or sorted.
My Tasks	An "Inbox" within MasterControl that is user specific. If there is anything in a user's My Tasks folder, that user has a task or action that they need to attend to.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Definitions (continued)

Packet Task	A task that is to be sent on a collaboration and/or approval route. A Packet task can contain one document or many documents and is up to the originator of the packet task to decide what is contained within the task, and the route that the task is to be sent on.
Redline	The term used to modify or update a document that is on a collaboration route. Redlining is to be done with the Track Changes function turned ON in Microsoft Word in order to see the revisions that have been made.

When creating a new document…

Use the appropriate Quality Management Systems standard document templates found in MasterControl.

Creating a new document InfoCard

Follow the steps below to create a new document InfoCard in MasterControl.

Step	Action
1	Log onto MasterControl, enter your User ID and Login password.
2	On the left hand side of the MasterControl Home Page screen, click on **Documents**. • click the **Create a New Document** folder icon, or • Click on **Documents**, and then click on **+ New**. The **Select InfoCard Type** window will appear.
3	• Select the appropriate document **InfoCard Type** for your location. Refer to **InfoCard Type Reference Chart** to assist you in your selection. The Subtype selection will appear. • Select the appropriate Subtype for your department and click **Continue**. The Document InfoCard screen will appear. ***Note:*** A Document number and Revision number will be automatically generated.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Creating a new document InfoCard (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4</td><td>In the Title field, copy and paste the exact title of the document as it appears in the document, and enter any applicable notes in the Notes field.</td></tr>
<tr><td>5</td><td>In the Other Information section, select the appropriate Author and Owner, and enter any Previous Number the procedure may have had.
<table>
<tr><th>If the…</th><th>Then…</th></tr>
<tr><td>Author is someone other than yourself</td><td>Click on the icon next to Author, and the Select A User screen will appear. Scroll to highlight the Author's name, and click OK.</td></tr>
<tr><td>Owner is someone other than yourself</td><td>Click on the icon next to Owner, and the Select A User screen will appear. Scroll to highlight the Owner's name, and click OK.

Note:
It is recommended that the <u>role</u> designated for the document owner in MasterControl is assigned as the document owner instead of an actual person.</td></tr>
</table></td></tr>
<tr><td>6</td><td>If the file is ready to be upload, click on the + icon in the Main File section next to File Name. The Add InfoCard Document File window will appear.
• Click Browse to locate the file to be uploaded, select the document file, and click Open. The document file name will appear in the File Name window.
• Click Load File. The document file name will appear in the File Name window in the Main File section.</td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Creating a new document InfoCard (continued)

Step	Action
7	• Click the Custom Fields tab. The Custom Fields screen will appear. • In the Value sections, scroll to and highlight custom field(s) in the *Available* section to be added to the *Selected* box by clicking the › Add Value(s) arrow. ***Notes:*** • Custom Fields is mandatory. • The custom field's value will allow a user to view the document in the appropriate organizer folder category in **My Organizer**.
8	• Review all information entered in the document InfoCard for accuracy and click **Save**. The 'InfoCard successfully saved' message will appear. • Delete the document electronic file from your computer.

Sending a document InfoCard for approval

Follow the steps below to send a document InfoCard for approval.

Step	Action
1	From the document infocard, click **Sign Off** and select **New Packet Task** from the dropdown menu. The **Start Task** screen will open.
2	In the **Task Information** section, enter a **Task Name**. ***Note:*** *If inputting a single document, it is recommended to enter the title (or an abbreviated version) of the document.*

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Sending a document InfoCard for approval (continued)

Step	Action
3	Optionally, in the **Task Information** section, enter applicable instructions in the **Instructions** field. ***Note:*** *These Instructions are also sent to those on the Notify Trainers step, in addition to the approvers.*
4	• In the **Route Information** section, select the appropriate Route Name from the dropdown list. ***Note:*** *There may only be a single option from the dropdown menu.* • Ensure that the appropriate route is selected by reviewing the **Route Description** with the **Available Route Steps** that will appear after selecting the Route Name.
5	In the **Change Request Information** section, enter the **Proposed Changes** *(*what you are changing*)* and **Reason for Change** *(*why you are changing*)*. ***Note:*** For new documents, it is sufficient to say something like "New Assay" or "New Form" in the **Proposed Changes** field.
6	Optionally, in the **Task Contents** + section, additional document changes can be added to the packet for revisions and/or new document infocards. Load any additional document InfoCards pertaining to the task by performing an InfoCard search, submitting the search, and retrieving the appropriate InfoCards.
7	Optionally, in the **Task Options** + section, attach any supporting information outside of MasterControl and/or add any supporting InfoCard links for reference only that pertain to the task in this section. ***Note:*** *For approver awareness, document in the **Instructions** field if attaching supporting information and/or adding supporting InfoCard links.*

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Sending a document InfoCard for approval (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>8</td><td>Launch the Packet Task now or at a later date.
<table>
<tr><th>If you wish to launch the packet task…</th><th>Then…</th></tr>
<tr><td>Now</td><td>Click Launch Task.</td></tr>
<tr><td>At a later date</td><td>Click the Save button to save the task and launch at a later time.
Launch the saved task later by going to My MasterControl, click Start Task, and click Packets.
Under Actions, click the launch icon of the packet task you want to launch.</td></tr>
</table>
Note:
When a packet task is successfully launched, the designated approver(s) will receive a task notification via e-mail, and the Change Request/New Document task will appear in the approver's My Tasks in MasterControl.</td></tr>
</table>

Approving Change Request Step

Follow the steps below to approve a new document or change request packet.

Note:
Only a single approval is required to move to the next Collaboration step.

Step	Action
1	Click on **My Tasks** in the **My MasterControl** page.
2	Under *Task Name*, select the packet that has the New Document or Change Request Step Name you would like to review, and click **Change Request** . The **View Task** page will appear.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Approving Change Request Step (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>3</td><td>Review the View Packet details that include information on:
• Any Instructions, Proposed Changes and Reason for Change
• The Task Contents section:
    • Click the View Document or icon to open and review the document, if the file was uploaded.
    • Click the View InfoCard icon to open and review the InfoCard in the Document InfoCard screen.
• Any other information and attachments pertaining to the packet.</td></tr>
<tr><td>4</td><td>Click Sign-Off to approve or reject the packet. The Sign Off Task: window will appear.</td></tr>
<tr><td>5</td><td>Select the appropriate Status from the dropdown menu.
<table>
<tr><td>If the packet is…</td><td>Then…</td></tr>
<tr><td>Approved</td><td>The Collaboration Packet Actions window will appear.
• Select Native.
• Click Continue.</td></tr>
<tr><td>Rejected</td><td>Your comment must be entered in the Comments section as to the reason for the rejection, and click Save.

Note:
The rejected packet is returned to the initiator's Start Task.</td></tr>
</table></td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Opening the Collaboration Packet

Follow the steps below to open the collaboration packet.

Step	Action
1	Click on **My Tasks**.
2	Under *Task Name*, select the packet that has the *Step Name* 'Collaboration', and click on the task name or **Collaborate** icon to open the **Collaboration Workspace** screen. ***Notes:*** • The Collaboration Workspace First -Time Help window will appear on your first collaboration. • Click the Close ⊠ icon to exit out of the window. The **Collaboration Workspace** screen will appear
3	For each department, it is recommended that a delegate (typically the Assistant Director) be identified as the Collaboration Leader. It is the Collaboration Leader's responsibility to finalize the file and end collaboration to route the documents for Initial/Final approval. <table><tr><td>If you are a…</td><td>Then follow <u>in order</u> the procedure blocks for…</td></tr><tr><td>Collaborator</td><td>1. Collaborating and redlining 2. Signing off Collaboration</td></tr><tr><td>Collaboration Leader</td><td>1. Collaboration Leader Only – Adding and/or deleting users 2. Collaborating and redlining 3. Signing off Collaboration</td></tr></table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Collaboration Leader Only – Adding and/or deleting users

Follow the steps below to add/delete users to the collaboration workspace.

Notes:

- Only a Collaboration Leader can add/delete users to the collaboration workspace by using the *Modify Step* icon in the My Tasks screen or Collaboration Workspace screen.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Determine if a user is to be added and/or deleted to the collaboration workspace.

<table><tr><td>If …</td><td>Then…</td></tr><tr><td>No users are to be added/deleted</td><td>Proceed to procedure block Collaborating and redlining.</td></tr><tr><td>Users are to be added/deleted</td><td>Proceed to Step 2.</td></tr></table></td></tr>
<tr><td>2</td><td>In the Collaboration Workspace screen, click Modify Step icon in the >Members section. The Modify Step window will appear.</td></tr>
<tr><td>3</td><td>• Scroll to and highlight a user in the Available section to be added to the Collaborators box by clicking the Add Step User arrow.
• Click the Remove Step User arrow to remove a user in the Collaborators and/or Leaders box.</td></tr>
<tr><td>4</td><td>Click Save, or click Undo Changes to discard all changes.</td></tr>
<tr><td>5</td><td>Enter your comments in the Change Reason window, and click Save. The Modify Step window will reappear with the message 'Successfully Modified Step'. Close the window.

Note:
If you attempt to add a user that does not have collaboration rights to the document vault, a message will appear informing you of that fact, in which case you should remove that user by highlighting the name and clicking on the Remove Step User icon.</td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Collaborating and redlining

Follow the steps below to collaborate and redline.

Step	Action
	Redlining
1	Click the *Collaboration Workspace* tab. • In the **All InfoCards** + section under **Collaboration Actions**, click the Edit File icon to open each file in its native application. • If a file was not previously uploaded to the new document infocard, a message may appear. If so, continue on with the "Uploading the Redlined InfoCard File" subsection. • Depending on the Browser version selected, a message may appear at the bottom of the window asking if you want to open or save the file. Select the desired option. ***Notes:*** • *If the document is locked, click the Unlock icon to access the Edit File icon. It is recommended to communicate with other team members regarding possible edits prior to unlocking. Only collaboration leaders or system administrators can unlock locked documents* • *If the browser window becomes blank, refer to the **Opening the Collaboration Packet** block to return to the **Collaboration Workspace**.*
2	Depending on the Microsoft Word version, click **Enable Editing** and/or enable **Track Changes** in Microsoft Word after opening the file, and make any necessary changes to the document.
3	Click **Save As**, and save the document in your computer where you can remember to retrieve it for uploading.
4	Close the document.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Collaborating and redlining (continued)

Step	Action
	Uploading the Redlined InfoCard File
5	In **Collaboration Actions**, click the Upload Changes icon to upload your changes to the document. The **Add Collaboration Redline** window will appear.
6	• Click **Browse,** locate the file in your computer, click Open, and click **Load File**. • Repeat Steps 4 and 5 for all InfoCards in the task that will need file changes to be uploaded. *Notes:* • If a collaborator does not have redlines to upload, the Collaboration Workspace must be unlocked so that other collaborators can access the file.
7	Under **Collaboration Actions**, click View Changes. The **View Redlines** window will appear. • Click View Redlines to open the document, and confirm that your modified document was uploaded. • Delete the file from your computer. • Repeat this step for all InfoCards in the task.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Collaborating and redlining (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td></td><td>Revision History and Collaboration Comments</td></tr>
<tr><td>8</td><td>Under Actions, click the Details icon (blue 'puzzle piece' icon). The Packet Item Details window will appear.
Complete the mandatory Change Description and Reason for Change fields.
Click Save. Repeat this step for all InfoCards in the task, if needed.
Important Notes:
The Packet Item Details will show in the approver's View Task screen where the approver can review the details of the packet before approval or rejection.
The Packet Item Details will reside in the Document InfoCard's history and will be used to verify the revision history for future inspections.</td></tr>
<tr><td>9</td><td>Click the Comments + icon if you wish to exchange ideas, document instructions and/or comments outside the context of the document before signing off.
Click the Save button. The comments are added to the Comments field.
<table><tr><th>If you are a…</th><th>Then…</th></tr><tr><td>Collaborator</td><td>Proceed to procedure block Signing off Collaboration</td></tr><tr><td>Collaboration Leader</td><td>Document the due date for redlines to other collaborators, if needed, and
Click Return tab.
Check other collaborators' progress and comments on the task by clicking Tracking under Actions in your My Tasks screen.
When the packet is ready to be sent for Initial/Final approval, proceed to procedure block Signing off Collaboration</td></tr></table></td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Signing off Collaboration

Follow the steps below for signing off in collaboration.

Notes:
- The Collaboration Leader is responsible for uploading the final document without redlines in the document InfoCard before approval.
- A Collaboration Leader can end collaboration at any time whether or not other collaborators have participated in the task.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Sign off on the collaboration task.

Notes:

If the Sign Off icon does not appear, click the Unlock icon. It is recommended to communicate with other team members regarding possible edits prior to unlocking.
If the user is finished working in collaboration, but would like to return again to make more redlines, DO NOT sign off on the collaboration task. Doing this will disable collaboration access, and will prevent the user from making further updates.

<table>
<tr><th>If you are a…</th><th>Then…</th></tr>
<tr><td>Collaborator</td><td>

Click Sign Off. The Sign Off on Collaboration window will appear.
Enter your Electronic Signature, and choose one of the following status options:

Complete – This means that you are signing off on the collaboration task for now, but would like it to return to you if someone else makes any changes to the document.
Complete & Quit – This means that you are signing off on the collaboration task, and you do not want it returned to you if someone else makes changes.

</td></tr>
<tr><td>Collaboration Leader</td><td>Proceed to Step 2 after the designated due date for redlines.</td></tr>
</table>
</td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Signing off Collaboration Collaboration (continued)

Step	Action
	Collaboration Leader Only
2	Create the final version of each document: • Review redlines by clicking the View Changes icon under **Collaboration Actions**. • Click the Edit File icon to open each file in its native application. • Modify/accept all changes in the document, click **Save As**, and close the document. • Click the Upload Changes icon to upload your modification/acceptance to the document.
3	Update the document infocard(s) information (if applicable): • Click the Edit File icon. • Click the link to the document under **Infocard Number** to go to the Infocard. • On the Infocard screen, click **Edit** > **Edit**. Make any changes (e.g. title, author, or custom fields). • Click the **Save** button. Enter **Change Reason**, and click the **Save** button. • Close the infocard, and return to the packet Collaboration screen. • *Click the Unlock icon to remove the lock on the infocard.*
4	Finalize revision history for each infocard: • Under *Actions*, click the **Details** icon (blue 'puzzle piece' icon). The **Packet Item Details** window will appear. • Review and enter/modify the **Change Description** and **Reason for Change** and click **Save**.

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Signing off Collaboration Collaboration (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>5</td><td>Upload the Final File to Each Infocard:
In the Collaboration Workspace tab under Actions, click the Replace File icon. The Replace InfoCard Main File window will appear.
Check the box Use Latest Redline, and click the Load File button.
Note:
The final version can also be uploaded by unchecking the Use Latest Redline option, selecting the final version by browsing to its location, and clicking the Load File button.</td></tr>
<tr><td>6</td><td>Click Sign Off . The Sign Off on Collaboration: window will appear.
Enter your comments, if any, your User ID and Electronic Signature.
Select one of the following Status options that may appear from the drop down menu, and click Save.
End Collaboration - This will end the collaboration and move the packet into the next route step.
<table>
<tr><th>If the following error displays…</th><th>Then…</th></tr>
<tr><td>All Infocards in collaboration require the Change description and Reason for Change fields to be populated.</td><td>Fill in the fields per Step 4 above.</td></tr>
<tr><td>The main files on the following InfoCards are older than the latest redline.</td><td>Update the final file per Step 5 above.</td></tr>
</table>
Abort Collaboration – This will abort or end the collaboration completely and permanently, and the packet will return to the initiator's Start Task.</td></tr>
</table>

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Packet Tracking for Initial/Final Approval

Follow the steps below to track the packet during initial/final approval.

Refer to "Approving and Implementing Documents in MasterControl" procedure for instructions on initial/final approval.

Step	Action
1	Click on **Tracking** in the **My MasterControl** page.
2	Click the **Search** button, and click the **Basic** tab.
3	The following search criteria (among others) are available: • **Task Name**: Useful for looking for a specific packet • **User ID**: Useful for looking for all of the packets you initiated. • **Route Name**: Useful for looking for all packets for a department.
4	• Click the **Submit Search** button. • Click the **Details** icon (blue 'puzzle piece' icon) under the far-right **Action** column. • Scroll down to the Initial Approval and Final Approval sections.

If your task gets rejected in the initial or final approval route

Follow the steps below if your task gets rejected by the initial or final approver.

Step	Action
1	Go to the **Opening the Collaboration Packet** block of this procedure to view the rejected task, and continue from that section. *Note:* *The **Rejection Comments** will be listed in the **Comments** section of the Collaboration Workspace.*

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Setting the effective date

Follow the steps below to set the effective date of the document in the task after initial/final approval.

Step	Action
1	Click on **My Tasks,** and click **Sign-Off** on the task you would like to view. The **View Task** screen will appear.
2	Review the details of the packet that includes the task contents and any task options.
3	Click **Sign Off**. The **Sign Off Task:** window will appear.
4	In the **Sign Off: Set Effective Date** section under **Dates**, click on Show dates.
5	In the **Effective Date** field, click on for today's date, or click the calendar icon to select another date. A two week period is a typically recommended time period to conduct training. ***Warning!*** *Do not place a date on the Expiration Date field as this is used for archiving documents only.*
6	Enter your User ID, Electronic Signature, and click **Save**. ***Notes:*** *The **Status** dropdown menu is preselected and fixed at the Approved status.* *The users assigned to the Notify Trainers step will be emailed after sign-off.*

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Creating and Collaboration of a Document Infocard in MasterControl, Continued

Non-Controlled Documents

The following non-controlled documents support this procedure.

- MasterControl Suite Online Help
- MasterControl Manual

Controlled Documents

The following controlled documents support this procedure.

Procedure
General Use of MasterControl
Approving Documents in MasterControl

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