

**DOCUMENT NUMBER:** 

**DOCUMENT TITLE:** 

**DOCUMENT NOTES:** 

LOCATION:

VERSION:

DOC TYPE:

STATUS:

**EFFECTIVE DATE:** 

NEXT REVIEW DATE:

**RELEASE DATE:** 

**EXPIRATION DATE:** 

**AUTHOR:** 

**PREVIOUS NUMBER:** 

**OWNER:** 

**CHANGE NUMBER:** 

This procedure provides instructions for creating and the process of collaboration of a document in MasterControl.		
All personnel trained in performing and implementing any of the activities described in this procedure.		
The table below lists the actions and responsible parties for this procedure.		
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**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.	

**Definitions** (continued)

	Packet 7	FaskA 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 <b>Documents</b> .	
		• click the Create a New Document folder icon, or	
		• Click on <b>Documents</b> , and then click on <b>Figure</b> . The <b>Select</b>	
		InfoCard Type window will appear.	
	3	<ul> <li>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.</li> <li>Select the appropriate Subtype for your department and click Continue. The Document InfoCard screen will appear.</li> </ul>	
		A Document number and Revision number will be automatically generated.	

Creating a new document InfoCard (continued)

Step	Action		
4	In the <b>Title</b> field, copy and paste the exact title of the document as it appears in the document, and enter any applicable notes in the <i>Notes</i> field.		
5	In the <b>Other Information</b> section, select the appropriate <i>Author</i> and <i>Owner</i> , and enter any <i>Previous Number</i> the procedure may have had.		
	If the	Then	
	Author is someone other than yourself	Click on the icon next to <i>Author</i> , and the <b>Select A User</b> screen will appear. Scroll to highlight the Author's name, and click <b>OK</b> .	
	Owner is someone other than yourself	Click on the icon next to <i>Owner</i> , and the <b>Select A User</b> screen will appear. Scroll to highlight the Owner's name, and click <b>OK</b> .	
		<i>Note:</i> 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.	
6	If the file is ready to be upload, click on the 🗣 icon in the <b>Main</b>		
	File section next to File Name. The Add InfoCard Document		
	File window will appear.		
	<ul> <li>Click Browse to locate the file to be uploaded, select the document file, and click Open. The document file name will appear in the <i>File Name</i> window.</li> <li>Click Load File. The document file name will appear in the <i>File Name</i> window in the Main File section.</li> </ul>		

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.		

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

Sending 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.	
	<i>Note:</i> <i>If inputting a single document, it is recommended to enter the title</i> <i>(or an abbreviated version) of the document.</i>	

Sending a document InfoCard for approval (continued)

Step	Action		
3	Optionally, in the Task Information section, enter applicable		
	instructions in the <b>Instructions</b> field.		
	Note:		
	These Instructions are also sent to those on the Notify Trainers		
4	step, in addition to the approvers.		
4	• In the <b>Route Information</b> section, select the appropriate Route		
	Note: There may only be a single option from the dropdown many		
	Note: There may only be a single option from the aropaown menu.		
	• Ensure that the appropriate route is selected by reviewing the		
	<b>Route Description</b> with the <b>Available Route Steps</b> that will		
	appear after selecting the Route Name		
5	In the <b>Change Request Information</b> section, enter the <b>Proposed</b>		
-	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 <b>Proposed Changes</b> 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 <b>Task Options</b> 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.		

#### Sending a document InfoCard for approval (continued)

Step	Action		
8	Launch the Packet Task now or at a later date.		
	If you wish to launch the packet task	Then	
	Now	Click Daunch Task.	
	At a later date	<ul> <li>Click the Save  button to save the task and launch at a later time.</li> <li>Launch the saved task later by going to My MasterControl, click Start Task, and click Packets.</li> <li>Under Actions, click the launch  icon of the packet task you want to launch.</li> </ul>	
	<i>Note:</i> 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.		

Approving<br/>ChangeFollow the steps below to approve a new document or change request packet.Request StepNote:

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.	

Approving Change Request Step (continued)

Step	Action			
3	Review the View Packet details that include information on:			
	• Any Instructions, Proposed Changes and Reason for Change			
	• The Task Contents	section:		
	• Click the View	w Document 🔤 or 🔤 icon to open and		
	review the door	cument, if the file was uploaded.		
	• Click the View	w InfoCard is icon to open and review the		
	InfoCard in th	e Document InfoCard screen.		
	• Any other information	n and attachments pertaining to the packet.		
4	Click Sign-Off a to approve or reject the packet. The Sign Off			
	Task: window will app	ear.		
5	Select the appropriate <b>Status</b> from the dropdown menu.			
	If the packet is	Then		
	Approved	The Collaboration Packet Actions		
		window will appear.		
		• Select Native.		
		• Click Continue.		
	Rejected	Your comment <b>must</b> be entered in		
		the <i>Comments</i> section as to the		
		reason for the rejection, and click		
		Save.		
		Note:		
		The rejected nacket is returned to		
		the initiator's <b>Start Task</b>		
		the initiator 5 Start Task.		

Opening the CollaborationFollow the steps below to open the collaboration packet.Packet			collaboration packet.	
	Step	Action		
	1	Click on My Tasks.		
	2	2 Under <i>Task Name</i> , select the packet that has the <i>Step Name</i>		
		'Collaboration', and click	on the task name or Collaborate 🔠 icon	
		to open the Collaboration	n Workspace screen.	
		Notes:		
		• The Collaboration Workspace First -Time Help window will appear on your first collaboration.		
		• Click the Close $\boxtimes$ ico	on to exit out of the window. The	
		Collaboration Work	space 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.		
		If you are a	Then follow <u>in order</u> the procedure blocks for	
		Collaborator	<ol> <li>Collaborating and redlining</li> <li>Signing off Collaboration</li> </ol>	
		Collaboration Leader	<ol> <li>Collaboration Leader Only – Adding and/or deleting users</li> <li>Collaborating and redlining</li> <li>Signing off Collaboration</li> </ol>	

Collaboration Leader Only – Follow the steps below to add/delete users to the collaboration workspace.

#### *Notes:*

Adding and/or deleting users

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

Step	Action		
1	Determine if a user is to be added and/or deleted to the collaboration workspace.		
	If	Then	
	No users are to be	Proceed to procedure block	
	added/deleted	Collaborating and redlining.	
	Users are to be added/deleted	Proceed to Step 2.	
2	In the <b>Collaboration Workspace</b> screen, click Modify Step icon in the <b>&gt;Members</b> section. The <b>Modify Step</b> window will appear.		
3	<ul> <li>Scroll to and highlight a user added to the <i>Collaborators</i> be User arrow.</li> <li>Click the S Remove Step Us Collaborators and/or Leaders</li> </ul>	in the <i>Available</i> section to be ox by clicking the Add Step ser arrow to remove a user in the box.	
4	Click Save, or click Undo Chang	ges to discard all changes.	
5	Enter your comments in the <b>Char</b> <b>Save</b> . The <b>Modify Step</b> window 'Successfully Modified Step'. Ch	<b>nge Reason</b> window, and click will reappear with the message lose the window.	
	<i>Note:</i> If you attempt to add a user that of to the document vault, a message fact, in which case you should rem name and clicking on the S Rem	loes not have collaboration rights will appear informing you of that move that user by highlighting the nove Step User icon.	

Collaborating Follow the steps below to collaborate and redline. and redlining Step Action Redlining 1 Click the Collaboration Workspace tab. In the All InfoCards 4 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 尾 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** ٠ the Collaboration Packet block to return to the Collaboration Workspace. Depending on the Microsoft Word version, click **Enable Editing** 2 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.

Collaborating and redlining (continued)

Step	Action			
	Uploading the Redlined InfoCard File			
5	In Collaboration Actions, click the Upload Changes 髦 icon to			
	upload your changes to the document. The Add Collaboration			
	Redline window will appear.			
6	• Click <b>Browse</b> , 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			
	<b>Redlines</b> 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.			

**Collaborating and redlining** (continued)

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

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.

Step	Action		
1	Sign off on the collaboration task.		
	<ul> <li><i>Notes:</i></li> <li>If the Sign Off icon does not appear, click the Unlock Sicon. <i>It is recommended to communicate with other team members regarding possible edits prior to unlocking.</i></li> <li>If the user is finished working in collaboration, but would like to return again to make more redlines, <b>DO NOT</b> sign off on the collaboration task. Doing this will disable collaboration access, and will prevent the user from making further updates.</li> </ul>		
	If you are a Then		
	Collaborator	<ul> <li>Click Sign Off. The Sign Off on Collaboration window will appear.</li> <li>Enter your Electronic Signature, and choose one of the following status options:</li> <li>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.</li> <li>Complete &amp; 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.</li> </ul>	
	Collaboration	Proceed to Step 2 after the designated due	
	Leader	date for redlines.	

Signing off Collaboration Collaboration (continued)

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

Signing off Collaboration Collaboration (continued)

Step	Action			
5	Upload the Final File to Each Infocard:			
	<ul> <li>In the Collaboration Workspace tab under <i>Actions</i>, click the Replace File → icon. The Replace InfoCard Main File window will appear.</li> <li>Check the box Use Latest Redline, and click the Load File button.</li> </ul>			
	<i>Note:</i> <i>The final version can also be uploaded l</i> <i>Latest Redline option</i> , selecting the fina <i>location, and clicking the Load File</i> but	by unchecking the <b>Use</b> I version by browsing to its ton.		
6	<ul> <li>Click Sign Off A. The Sign Off on Collaboration: window will appear.</li> <li>Enter your comments, if any, your User ID and Electronic Signature.</li> <li>Select one of the following Status options that may appear from the drop down menu, and click Save.</li> <li>End Collaboration - This will end the collaboration and move the packet into the next route step.</li> </ul>			
	If the following error displaysAll Infocards in collaboration requirethe Change description and Reason forChange fields to be populated.The main files on the followingInfoCards are older than the latestredline.	Then Fill in the fields per Step 4 above. Update the final file per Step 5 above.		
	<ul> <li>Abort Collaboration – This will collaboration completely and per will return to the initiator's Start</li> </ul>	l abort or end the rmanently, and the packet t <b>Task</b> .		

Packet Tracking for	Follow the steps below to track the packet during initial/final approval.
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 <b>Submit Search</b> button.		
	• Click the <b>Details</b> icon (blue 'puzzle piece' icon) under the		
	far-right Action column.		
	• Scroll down to the Initial Approval and Final Approval		
	sections.		

If your taskFegets rejected inalthe initial orfinal approvalrouteroute

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

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

Setting the effective date	Follow the follow the follow the follow the following the	he steps below to set the effective date of the document in the task ial/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 <b>Effective Date</b> field, click on <sup>(b)</sup> 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:
		<i>The</i> <b>Status</b> <i>dropdown menu is preselected and fixed at the Approved status</i> .
		The users assigned to the Notify Trainers step will be emailed after sign-off.

Non-Controlled Documents	The following non-controlled documents support this procedure.		
	<ul><li>MasterControl Suite Online Help</li><li>MasterControl Manual</li></ul>		
Controlled Documents	The following controlled documents support this procedure.		
	Procedure		
	General Use of MasterControl		
	Approving Documents in MasterControl		
Author	Emeline Santos, SCPMG Quality Assurance Coordinator Matthew Jones, SCPMG Systems Consultant		

#### Document Number: SCPMG QMS - 0008

Title: Creating a New Document InfoCard in MasterControl

All dates and times are in Pacific Standard Time.

#### MasterControl PPP Updates

#### **Initial Approval**

Name/Signature	Title	Date	Meaning/Reason
Fred Ung (K057175)	SCPMG LABORATORY QCD	26 Jul 2016, 03:29:24 PM	Approved
Maureen Ahler (K083442)	Quality Systems Leader	01 Aug 2016, 03:38:36 PM	Approved

#### **Final Approval**

Name/Signature	Title	Date	Meaning/Reason
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	08 Aug 2016, 06:10:41 PM	Approved
Darryl Palmer-Toy (T188420)	SCPMG Laboratory Sys Med Dir	13 Aug 2016, 05:02:34 PM	Approved

#### Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Aidzz Ticsay (K109967)	Regional QA Coordinator		
Emeline Santos (K082273)	Regional Quality Assurance CD		
Maureen Ahler (K083442)	Quality Systems Leader	14 Aug 2016, 07:10:40 PM	Approved