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DOCUMENT TITLE: Approving Documents in MasterControl
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Approving Documents in MasterControl

Purpose This procedure provides instructions for approving documents in MasterControl.

Scope All personnel trained in performing 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

Approved Document	A document maintained in MasterControl which has been approved with an electronic signature by the appropriate CLIA Director, or designee, and which has been assigned an effective date. Approved documents are housed in a Released Vault within MasterControl.
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 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.

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Approving Documents in MasterControl, Continued

Definitions (continued)

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.
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.





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Approving Documents in MasterControl, Continued

Initial or final approval of documents

Follow the steps below for initial and/or final approval of documents.

Refer to the "Revising a Document in MasterControl" and "Creating a New Document InfoCard in MasterControl" procedures for further instructions.

Step	Action						
1	Log onto MasterControl, enter your User ID and Login password.						
2	Click on My Tasks , and click Sign-Off  on the task you would like to review for approval. The View Task screen will appear.						
3	Review the details of the packet that includes the task contents and any task options. <i>Note:</i> Click on  or  to view each document needing review and approval.						
4	Click  Sign Off . The Sign Off Task: window will appear.						
5	Enter your Electronic Signature, and select the Approved or Rejected Status from the dropdown menu. <table border="1"> <thead> <tr> <th>If...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>Approved</td> <td> <ul style="list-style-type: none"> Click Save. The task is automatically moved to the next step in the route. </td> </tr> <tr> <td>Rejected</td> <td> <ul style="list-style-type: none"> Enter your comments in the Comments field, and click Save. The task is automatically returned to the collaboration step in the initiator's My Tasks inbox. </td> </tr> </tbody> </table>	If...	Then...	Approved	<ul style="list-style-type: none"> Click Save. The task is automatically moved to the next step in the route. 	Rejected	<ul style="list-style-type: none"> Enter your comments in the Comments field, and click Save. The task is automatically returned to the collaboration step in the initiator's My Tasks inbox.
If...	Then...						
Approved	<ul style="list-style-type: none"> Click Save. The task is automatically moved to the next step in the route. 						
Rejected	<ul style="list-style-type: none"> Enter your comments in the Comments field, and click Save. The task is automatically returned to the collaboration step in the initiator's My Tasks inbox. 						

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Approving Documents in MasterControl, Continued

Non-Controlled Documents The following non-controlled documents support this procedure.

- MasterControl Suite Online Help
 - MasterControl Manual
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Controlled Documents The following controlled documents support this procedure.

Procedure
General Use of MasterControl
Revising a Document in MasterControl
Creating a New Document InfoCard in MasterControl

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Signature Manifest

Document Number: SCPMG QMS - 0010

Revision: 4

Title: Approving Documents 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