

eLogs

Florence's solution to fillable logs

Solving the DOA Workflow

Principal Investigator: Peter Smith, MD Delegation of Authority and Staff Signature Log Page 1 of 2 08/25/2020
 Protocol Title: Study ABC
 IRB Number: 12345

Print Name	Study Role	Study Specific Tasks	Signature	Initials	Dates of Responsibilities		PI Approval (PI Initials and Date)
					Start Date	End Date	
Dr. Smith Peter Smith, MD	PI	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20		PS	08/25/20	08/25/20	PS 08/25/2020
Nikki Taylor	RC	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	Nikki K. Taylor	NKT	29 SEP 2020	29 SEP 2020	PS 29 SEP 2020
J. Robert Handy	Co-SubI	1, 2, 3, 4, 5	J. Robert Handy	JRH	9/21/20		PS 28 SEP 2020
Raul Smiley	SubI	1, 2, 3, 4, 5, 6, 7, 8					NKT 29 SEP 2020
Andrew Paully	SubI	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20		AP	29 SEP 2020		PS 29 SEP 2020
Deanna Alder	RN	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19	Deanna Alder	DA	29 SEP 2020		PS 29 SEP 2020
Patricia Blatt	Pharmacist	9, 10, 11		PB	29 SEP 2020	29 SEP 2020	PS 29 SEP 2020

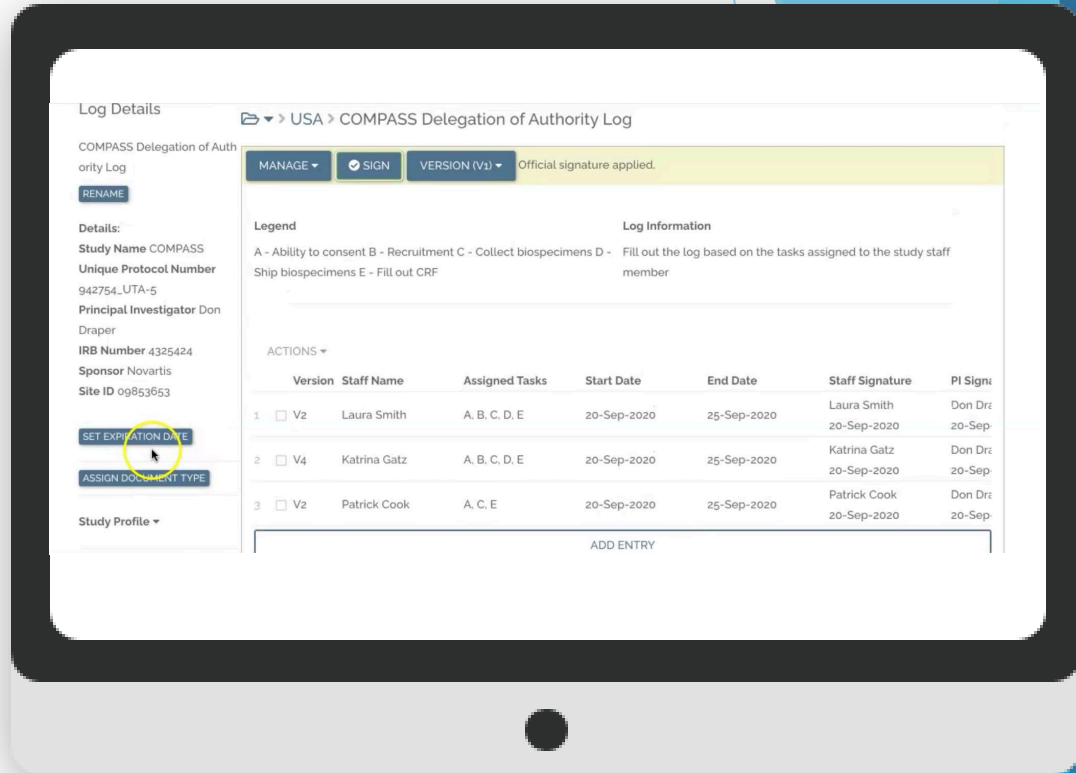
End of Study
 Principal Investigator Signature: Date: 29 SEP 2020

Handwritten notes: "PI approval - Study end" (next to Dr. Smith), "NKT 29 SEP 2020" (next to Nikki Taylor), "ERROR NKT 30 SEP 2020" (next to Patricia Blatt), "Image upload" (next to task 24).

Role	Signature	Date
Principal Investigator		29 SEP 2020
Research Coordinator		
Pharmacist		
Sub-Investigator		
Research Nurse		
Other:		

Study Specific Tasks:

- Obtain informed consent
- Subject selection/recruitment
- Confirm eligibility (review Inclusion/exclusion criteria)
- Obtain medical history (source documents)
- Perform physical exam
- Conduct study visit procedure as outlined in the protocol
- Make study-related medical decisions
- Assess AEs/SAEs
- Dispense study drug
- Perform drug accountability
- Study drug storage and temperature monitoring
- Sample collection
- Sample processing and/or shipment
- Evaluate study-related test results
- Use IWRS/IVRS
- Make entries/corrections on (e)CRFs
- Sign-off on (e)CRFs
- Maintain essential documents
- Perform study-related assessments as per protocol
- Regulatory submissions
- Billing/Finance
- Project Management
- Other (specify)
- Other (specify)



eLogs allows you to create and maintain logs within Florence so you can track your research activities. You can create log templates for your team so that everyone has a standardized way of recording and storing data. With eLogs, you can create entries, edit entries, request signatures, and sign (both entries and the entire log).



Getting Started

The screenshot shows the Florence web application interface. At the top, the logo "Florence" is on the left, and "Placebo Pharmaceuticals Clinical Studies" is in the center. On the right, there are "Settings" and "Lauren Martin" dropdown menus. The main content area is titled "Binders" and includes a "CREATE BINDER" button, an "ACTIONS" dropdown, and a "Filter by..." input field. Below this is a table of binders with columns for "Name", "Modified", and "Actions". A settings menu is open, with "Log Templates" highlighted in a green box.

Name	Modified	Actions
<input type="checkbox"/> 0. Georgia Oncology Site Credentials		
<input type="checkbox"/> 01 Test Binder	09-Nov-2020 @ 1:06 PM EST	
<input type="checkbox"/> 01. Study Binder 123	14-Oct-2020 @ 2:33 PM EST	
<input type="checkbox"/> 02 Dashboard Example	22-Oct-2019 @ 9:14 AM EST	

Tip: There are permissions required to use and create eLogs.

How?

First, create a log template

- Locate "Log Templates" under the settings tab at the upper right as shown in red.

Note: if you do not see this - your site admin will need to grant you the permission to create logs!

Create your Templates

The screenshot shows the Florence application interface for 'Placebo Pharmaceuticals Clinical Studies'. The user is Lauren Martin. The page is titled 'Log Templates'. A 'CREATE TEMPLATE' button is highlighted with a green box. Below it is a table of existing templates.

Template Name	Date Modified	Date Created	Actions
<input type="checkbox"/> Test template	11-Nov-2020 @ 2:24 PM EST	11-Nov-2020 @ 2:24 PM EST	⋮
<input type="checkbox"/> Training Log	07-Oct-2020 @ 12:10 PM EST	07-Oct-2020 @ 12:10 PM EST	⋮
<input type="checkbox"/> Enrollment Log	13-Oct-2020 @ 4:48 PM EST	13-Oct-2020 @ 4:48 PM EST	⋮
<input type="checkbox"/> Delegation of Authority Log 11Oct2020	13-Oct-2020 @ 5:12 PM EST	13-Oct-2020 @ 5:12 PM EST	⋮
<input type="checkbox"/> Site Visit Log	15-Oct-2020 @ 10:43 AM EST	15-Oct-2020 @ 10:43 AM EST	⋮
<input type="checkbox"/> Test 2	16-Oct-2020 @ 11:50 AM EST	16-Oct-2020 @ 11:50 AM EST	⋮
<input type="checkbox"/> Individual Training Log (AP)	15-Oct-2020 @ 2:48 PM EST	15-Oct-2020 @ 2:48 PM EST	⋮
<input type="checkbox"/> No Signature Required	20-Oct-2020 @ 7:57 AM EST	20-Oct-2020 @ 7:57 AM EST	⋮

Next, click on 'CREATE TEMPLATE' as shown highlighted. You are ready to build your template



Build your Template part 1

Log Templates > Create Log Template

* Template Name

Please provide a name for this Log Template

* Log Details: Enter header/log information

Study Name



Unique Protocol Number



Principal Investigator



IRB Number



Sponsor



ADD DETAIL

Give the template a name, understanding this template can be sent to multiple studies. Name examples: "DOA Log", "Monitor Visit Log", or Sponsor-specific, like "<Sponsor Name> DOA Log"

The Log details are the study-specific details that will be filled out for each study you send this template to. You can add or remove any details needed for the template.

Build your Template part 2

Legend
Example: A - Ability to consent

General Information
Example: Instructions on how to fill out the log

*** Log Columns:** Enter column header and specify column type

Enter Column Header

Text

ADD COLUMN

Version Comments Will be stored in the audit trail

Please provide a version comment for this Log Template (optional)

SAVE

- The legend should be used to reduce the amount of space you need to take up in columns like “Delegation” or “Reason for Monitor Visit”.
- Build your legend, and explain how it should be used in “General Information”
- To add and select the parameters for your columns, begin typing in the box that says ‘Enter Column Header’ then select if it will be text, a date, or a signature. Click the blue ‘Add Column’ button.
- Finish by providing comments on the version you’ve created, and click “Save”

Add Template to Study

Florence Placebo Pharmaceuticals Clinical Studies Settings Lauren Martin

Search

Announcements

Global View

Binders

Reports

Dashboard

My Downloads

Need Help?

Import Documents

Drag files here or **browse**.

IMPORT VIA EMAIL

Binders > 01 Test Binder

CREATE NEW ACTIONS Filter by...

- Folder
- Import Shortcuts
- Placeholder
- Log

	Count	Last Modified	Actions
<input type="checkbox"/> Placeholder		07-Oct-2020 @ 12:42 PM EST	⋮
<input type="checkbox"/> FDA-1572		25-Jun-2020 @ 2:43 PM EST	⋮
<input type="checkbox"/> financialDisclosure		03-Nov-2020 @ 10:43 AM EST	⋮
<input type="checkbox"/> FinancialDisclosure		31-Jan-2020 @ 9:27 AM EST	⋮
<input type="checkbox"/> Flo Cert Mindflash Outline		16-Aug-2019 @ 12:22 PM EST	⋮
<input type="checkbox"/> Flo Cert Mindflash Outline - Shortcut		12-Jun-2019 @ 7:16 PM EST	⋮

- Navigate to the location where the eLog should live
- From "Create New", select "Log"

Naming your Log

*** Name (this can be changed later)**

Length must be between 1 and 250 characters and may consist of any characters except the following \ / : < > " | ? *

*** Template**

- Name your log a study-specific name, following your naming convention
- Enter the Template name you'd like to use for this log

Complete Log Details

Edit Log Details ✕

Placebo Pharmaceuticals Clinical Studies / ... / Template

IRB Number

Principal Investigator

Site Name

Site Number

Sponsor

Study Name

Unique Protocol Number

- When you open your log for the first time, you'll be asked to enter the log details that were created in the Template creation.
- **Note:** If you skip this step, this pop-up will appear every time someone opens the log until the fields are completed. Florence recommends completing these fields the first time you open the log to avoid confusion.

Build your Logs

Search 01 Test Binder > Template

Log Details

MANAGE SIGN VERSION (V1)

Template

RENAME

Details:

Study Name Study XYZ
Unique Protocol Number 123
Principal Investigator Martin
IRB Number 1234
Sponsor Sponsor A
Site Name Sample Site
Site Number Sample Number

SET EXPIRATION DATE

ASSIGN DOCUMENT TYPE

Study Profile

Template Version:
Delegation of Authority Log
11Oct2020 V2

Legend

A- Informed Consent Process
B- Eligibility assessment
C- CRF completion
D- Obtain medical history
E- regulatory documentation
F- Concomitant medication review
G- perform physical exam
H- Review lab and procedure results
I- IP accountability

Log Information

Use activity codes to delegate tasks to the responsible individual.
Please amend activities as appropriate for your study

ACTIONS

Version	Staff member	Role	Delegated Tasks	Start Date	End Date	Staff Si
ADD ENTRY						

- Your log details will show on the left side of the log
- Your legend will appear at the top of the log, to the left of the instructions on how to use the legend
- Start adding log entries by clicking "Add Entry"

Adding Entries

Version	Test Name	Staff Signature	PI Signature	Signature	Actions
V1	<input type="text" value="Test Name"/>	<input type="text" value="Staff Signature"/>	<input type="text" value="PI Signature"/>	<input type="text" value="Signature"/>	
Comment					
<input type="text" value="Example: reasons for adding or editing entry"/>					
<input type="button" value="CANCEL"/> <input type="button" value="SAVE & ADD ANOTHER"/> <input type="button" value="SAVE"/>					

- Depending on how many columns you have, there may be a horizontal scroll with your log entries.
- Fill out the information you have, and save & add a new row, or just save the row you created.
- Continue adding as many rows as you need!

Completed Rows

MANAGE ▾ SIGN VERSION (V1) ▾

ACTIONS ▾

	Staff Signature	PI Signature	Signature	Actions
artin	Click to Sign	Click to Sign	Click to Sign	⋮
osenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

Audit Trail
Edit
Sign
Request Signatures

- Once you've created your rows, you can utilize the Actions dropdown by selecting the row you want to act on. View the audit trail, edit, sign a row or request signatures on a particular row. All actions you can take on a row will take place using this Actions dropdown.
- Note: This is a new workflow! Request signatures on rows using the Actions dropdown, NOT the "Manage" dropdown

Versioning Rows

MANAGE ▾ SIGN VERSION (V1) ▾

ACTIONS ▾

	Version	Test Name	Staff Signature	PI Signature	Signature	Actions
1	<input checked="" type="checkbox"/> V2	Lauren Jenna Martin	Click to Sign	Click to Sign	Click to Sign	<input checked="" type="checkbox"/> ▾
2	<input type="checkbox"/> V1	Lauren Rosenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

After editing a row, you'll automatically create a new version for that row specifically. You can view changes made to that row by clicking the caret on the right side of the row.

Viewing Changes

MANAGE ▾ SIGN VERSION (V1) ▾

ACTIONS ▾

	Version	Test Name	Staff Signature	PI Signature	Signature	Actions
1	<input checked="" type="checkbox"/> V2	Lauren Jenna Martin	Click to Sign	Click to Sign	Click to Sign	⋮ ^
	V1	Lauren Martin				
2	<input type="checkbox"/> V1	Lauren Rosenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

Changes made will show as bold in previous versions

Requesting Signatures

Potential Signer(s)

If you would like the selected user(s) to receive an email now, select the "Email" checkbox for each User. If you would like to be emailed an alert once the user signs this document, select the "Alert" checkbox for each User.

<input type="checkbox"/>	Name	Column*	Reason*	Sign By Date	Alert	Email
<input type="checkbox"/>	Lauren Martin	Select a column ▼ Staff Signature PI Signature Signature	Select a Reason ▼	None	<input type="checkbox"/>	<input type="checkbox"/>

Add Comment

0 / 500

- Requesting signatures will pull up the same familiar module, with one change: You'll select the column you're requesting the signature on.
- Even if you only have one signature column, you need to select the signature column field.

Signing the Log

MANAGE ▾ SIGN ✓ VERSION (V1) ▾

ACTIONS ▾

	Version	Test Name	Staff Signature	PI Signature	Signature	Actions
1	<input type="checkbox"/> V2	Lauren Jenna Martin	Pending my Signature	Click to Sign	Click to Sign	⋮ ▾
2	<input type="checkbox"/> V1	Lauren Rosenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

When the user signs in to view the log, their requested signature column will show as yellow. The user will simply click their yellow column to sign the log.

Signing the Log

Save Signature Template

Placebo Pharmaceuticals Clinical Studies / ... / Template

I, **lauren.martin@florencehc.com**, am authorizing 1 signature:

* **Column**

Staff Signature

* **Reason**

Acknowledge

* **Password**

* Required by **21 CFR Part 11**

CANCEL

SAVE

- Once you click the yellow signature field, you'll confirm the column you're signing as well as the reason.
- Enter your password or signing PIN and click Save to store your signature on the log

Confirming Signature

The screenshot displays the Florence HC interface. A white confirmation popup is centered on the screen, reading: "Congrats - Your document is signed!" followed by "You've completed all your signature requests. Have a great day!" and a "RETURN TO DOCUMENT" button. In the background, a green notification bar says "Document signed successfully." Below this, a table lists signature requests with columns for Version, Test Name, Staff Signature, PI Signature, and Signature. The first row shows a request for Lauren Jenna Martin, with a date of 11-Nov-2020 and "Click to Sign" buttons for PI and Signature. The second row shows a request for Lauren Rosenzweig with "Click to Sign" buttons for all three categories. An "ADD ENTRY" button is at the bottom of the table.

Version	Test Name	Staff Signature	PI Signature	Signature	Actions
1 <input type="checkbox"/> V2	Lauren Jenna Martin	Lauren Martin 11-Nov-2020	Click to Sign	Click to Sign	⋮ ▾
2 <input type="checkbox"/> V1	Lauren Rosenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

You'll still receive the familiar Green and White confirmation of success popups you've grown used to while using Florence!

Signatures

MANAGE ▾ SIGN VERSION (V1) ▾

ACTIONS ▾

	Version	Test Name	Staff Signature	PI Signature	Signature	Actions
1	<input type="checkbox"/> V2	Lauren Jenna Martin	Lauren Martin 11-Nov-2020	Click to Sign	Click to Sign	⋮ ▾
2	<input type="checkbox"/> V1	Lauren Rosenzweig	Click to Sign	Click to Sign	Click to Sign	⋮

ADD ENTRY

Signatures will fit neatly under the column header, without needing to resize or guess where to place the signature.

Signature on a Row



Placebo Pharmaceuticals Clinical Studies

Settings

Chris R. Longname

Search

Log Details

[My Signature Queue](#)
Sign on Row 2

[Next \(1 of 2\)](#)

[My Task Queue](#)

[Start Tasks \(3\)](#)

Delegation of Authority
Log 12Jan2021

[Delegation of Authority](#) > [Delegation of Authority Log 12Jan2021](#)

RENAME

Details

Study Number:

409570475

Principal Investigator:

Katrina Smith

IRB Number: 094285049

UPDATE EXPIRATION DATE

Document Creation

12-Jan-2021

MANAGE SIGN DECLINE VERSION (V3)

Legend
A - Recruit Participants
B - Informed Consent
C - Collect Biological Samples
D - Regulatory Documentation

Log Information
Fill out the log using the legend with the appropriate information.

ACTIONS

	Version	Staff Member	Delegated Tasks	Start Date	End Date	Staff Signature	PI Signature	Actions
1	<input type="checkbox"/> V1	John Marx	A, B, C, D	12-Dec-2020		Click to Sign	Kathryn Meagley 12-Jan-2020	⋮
2	<input type="checkbox"/> V1	Luke Skywalker	A, B, C, D	12-Dec-2020		Click to Sign	Pending My Signature	⋮



Audit Trail

Audit Trail

Placebo Pharmaceuticals Clinical Studies / 01 Test Binder / Template

NAME Filter by...

Download as CSV Download as PDF

Name	Action	Who	When
01 Test Binder/Template Log Entry Row: 1	Log Entry Signed	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:31 PM EST
Reason: Signed for Acknowledge			
01 Test Binder/Template Version: 1	Log Viewed	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:30 PM EST
01 Test Binder/Template Log Entry Row: 1	Log Entry Signature Requested	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:30 PM EST
01 Test Binder/Template Log Entry Row: 1	Log Entry Updated	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:29 PM EST
01 Test Binder/Template Log Entry Row: 1	Log Entry Created	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:28 PM EST
01 Test Binder/Template Version: 1	Log Details Updated	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:27 PM EST
01 Test Binder/Template Version: 1	Log Viewed	Lauren Martin - lauren.martin@florencehc.com	11-Nov-2020 @ 2:26 PM EST

View the audit trail of the entire log or select a row to view a specific audit trail as needed.