



eISF/eBinders™ Workflows & eSignature Reference Guide for Commercially Sponsored Studies



Workflow 1

ADDENDUM
Signatures

(Documents where the signature does not need to be visible on the document)

eSignature Request Process:

1. Select Manage → "Request Signature"
2. Select Potential Signers(s), choose Addendum as type, signature reason, and Sign By Date if desired. Check "Alert" to be notified upon signing and "Email" to send email notification to requested signer (Recommended).
3. Add comments to signer(s) if desired.
4. Click "SAVE"

Workflow 2

STAMP
Signatures

VISIBLE Signature
ON Documents Required

(Non forms, such as CVs)

eSignature Request Process:

1. Select Manage → "Request Signature"
2. Select Potential Signers(s), choose Stamp as type, signature reason, and Sign By Date if desired. Check "Alert" to be notified upon signing and "Email" to send email notification to requested signer (Recommended).
3. Add comments to signer(s) if desired.
4. Click "SAVE"

Workflow 3

FORM Signatures with **yellow signature box**

VISIBLE Signature
ON Documents where **specific location** of signature is predetermined

(Forms, such as 1572, Financial Disclosures)

Fillable Form Process:

1. Upload approved Form. Confirm the form displays correctly in eBinders and eSignature box is yellow.
2. Complete fillable fields, select "SAVE" and then "**SAVE DRAFT**" if someone else will be signing. This will maintain the yellow signature box.

eSignature Request Process:

1. Select Manage → "Request Signature"
2. Select Potential Signer, signature reason, and Sign By Date if desired. Check "Alert" to be notified upon signing and "Email" to send email notification to requested signer (Recommended).
3. Add clear instructions in comments and click "SAVE"

*** When user signs they MUST finalize the form.**

Workflow 4

No signature required

Simply upload document. No signature actions required.

Document	Signature Type (Addendum, Stamp, Form, or N/A)	Signature Reason (Acknowledge, Approval, Authorship, Responsibility, or Review)	Work Flow	Notes
Cancellation Agreement	Stamp	Approval	2	
Clinical Trial Research Agreement	Stamp	Approval	2	- Import writable form - Note, not all CTRAs may be able to be executed/signed via Florence
Confidentiality Agreement	Stamp	Approval	2	
Continuing Review	Addendum	Acknowledge	1	
Data Privacy Agreement	Form	Approval	3	
Delegation of Authority Log	Form/eLog	-Responsibility	3	- Can also be imported as Import Writable Form - Florence eLog
DSMB Reports	Addendum	Acknowledge	1	
DSUR	Addendum	Acknowledge	1	
FDA 1572 Form	Form	Approval	3	- Import Writable Form;
Financial Disclosure	Form	Approval	3	- Import Writable Form
IB Receipt Page	Stamp	Acknowledge	2	- Only if applicable
ICH-GCP Attestation Page	Form	Approval	3	- Import Writable Form
Medical Device Annual Report	Addendum	Acknowledge	1	
Note to File – from Team	Form	Authorship	3	- Import Writable Form
Note to File – from Sponsor to Site	Form	Acknowledge	3	- Import Writable Form
Protocol Agreement & Signature Page	Stamp	Acknowledge	2	
Site Monitoring Visit Log	eLog	Acknowledge	3	- Florence eLog
Site Visit Log	eLog	Acknowledge	3	- Florence eLog
Staff CVs	Form Stamp	Approval Authorship	3-2	
Staff Privacy Information Consent Form	Form	Acknowledge	3	
SUSAR Line Listing	Addendum	Acknowledge	1	
Training Log – Site Specific	Form eLog	Non-PI: Acknowledge PI: Approval	3	- Import Writable Form; or - Florence eLog

*****Please refer to the next page for a generic list of study documents which do not require eSignatures*****

QUESTION?

Reach out to the following positions for questions on any items (including workflows designated as OTHER):

MCRI Florence Organisational Administrator:
Florence@mcri.edu.au

Study Documents not requiring Signature Workflows within the eISF/eBinders™

Document	Signature Type <i>(Addendum, Stamp, Form, or N/A)</i>	Work Flow	Notes
Adverse Events Log	NA	NA	- Not required, filed outside of Florence
Biospecimen Collection Log	eLog	4	- Florence eLog
Consent Forms	NA	NA	- Not required, filed outside of Florence
Eligibility/Enrolment Forms	Form	4	
Enrolment Log – Site Specific	eLog	4	- Florence eLog
IB or Package Inserts	NA	4	
Investigational Brochure Version Tracker	eLog	4	- Florence eLog
IRB/HREC Approvals	NA	4	
IRB/HREC Roster	NA	4	
Laboratory Reference Ranges / Lab Normals	NA	4	
Manual of Procedures	NA	4	
Medical Licenses	NA	4	
Monitoring Close-Out Report	NA	4	
Monitoring Correspondence	NA	4	
NATA Accreditation Certificate	NA	4	
Newsletters	NA	4	
Other Agreements - i.e. External Service Providers	NA	4	
Patient ID Log	eLog	4	- Florence eLog
Pre Screening Log	eLog	4	- Florence eLog
Protocol	NA	4	
Protocol Deviation Form	NA		- Not required, filed in EDC with Sponsor
Protocol Deviation Log	NA		- Not required, filed in EDC with Sponsor
PICF Version Tracker	eLog	4	
Recruitment Material	NA	4	
SAEs – completed Initial & Follow Up Forms	Wet-Ink	4	
Screening Log	eLog	4	- Florence eLog
Serious Breaches & Suspected Serious Breaces Report Form	NA	4	- Completed via the ERM for Australian Sites
Site Activation Letter	NA	4	
Site Initiation Attendance Log	Wet-Ink	4	

Study Documents not requiring Signature Workflows within the eISF/eBinders™

Document	Signature Type <i>(Addendum, Stamp, Form, or N/A)</i>	Work Flow	Notes
Sponsor Correspondence	NA	4	
Sponsor Site Staff Consent Form	NA	4	
Staff Licenses – AHPRA	NA	4	
Staff Training (Protocol and Amendment Training)	NA	4	
Staff Training Certificates (GCP, EDC, HIPAA, etc)	NA	4	
Subject Reimbursement Form	NA	4	
Wet-Ink Signature Log	Wet-Ink	4	