eISF/eBinders™ Workflows & eSignature Reference Guide for Investigator-Initiated Studies

Florence

murdoch children's research institute

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 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	*Signature Requested From (CPI/Trial Coordinator/Statistician/Data manager/Other)*	*Notes*
Clinical Trial Research Agreement	Form	Acknowledge	3	- MCRI COO (alert PA) - Participating Site Authorised Representative Participating Site PI	- Import writable form - Note, not all CTRAs may be able to be executed/ signed via Florence
Delegation of Authority Log – Central Team	Form eLog	Non-PI: Acknowledge PI: Approval	3	All members from the Participating Site team involved within the study	- Import Writable Form; or - Florence eLog
FDA 1572 Form	Form	Approval	3	- Site PI - Site Sub-Investigators	- Import Writable Form; - Only required for studies under an IND
Financial Disclosure (Sponsor Provided)	Form	Approval	3	- CPI - All listed CI's	- Import Writable Form
IB Receipt Page – Site PI Acknowledged	Stamp	Acknowledge	2	- Site PI	- Only if applicable
Investigator Agreement to Archive – Site PI Acknowledged	Form	Acknowledge	3	- Site PI	- Import Writable Form
Monitoring Close-Out Report – Site Specific	Form	Acknowledge	3	- Site PI	- Import Writable Form
Note to File – from Participating Site to Sponsor	Form	Acknowledge	3	- CPI - Sponsor Representative, if applicable	- Import Writable Form
Note to File – from Sponsor to Participating Site	Form	Acknowledge	3	- Site PI	- Import Writable Form
Other Agreements (i.e. MTAs/Data Sharing Agreements etc)	Form	Acknowledge	3	- MCRI COO (alert PA) - Participating Site Authorised Representative - MCRI Legal - Others, as required	- Import Writable Form - Not all Agreements may be able to be executed/signed via Florence
Principal Investigator Declaration Form	Form	Acknowledge	3	- Site PI	- Import Writable Form
Protocol Agreement & Signature Page – signed by Site PI	Form	Acknowledge	3	- Site PI	- Import Writable Form
Non-Compliance Report Form	Form	Acknowledge	3	- Site PI	- Import Writable Form
Non-Compliance Report Review Form	Form	Acknowledge	3	- Site PI	- Import Writable Form
Source Document Plan – Site Specific	Form	Acknowledge	3	- Site PI	- Import Writable Form
Site Monitoring Visit Log	Form	Acknowledge	3	- Site PI	- Import Writable Form
Staff CVs	Stamp	Approval	2	All members from the Participating Site Team involved within the study	
Training Log – Site Specific	Form eLog	Non-PI: Acknowledge PI: Approval	3	All members from the Participating Site Team involved within the study	- Import Writable Form; or - Florence eLog

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

Document	Signature Type *(Addendum, Stamp, Form, or N/A)*	Work Flow	Notes
Adverse Event Log	NA	NA	- Not required, filed outside of Florence
Annual Safety Reports	NA	4	- Completed via the ERM for Australian Sites
CAPA Tracking Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Consent Forms	NA	NA	- Not required, filed outside of Florence
DSUR	NA	4	
Enrolment Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Ethics Committee Submission & Approvals - Initial Application	NA	4	
Ethics Committee Submission & Approvals - Subsequent Applications & Amendments	NA	4	
Ethics Committee Continuing Review Acknowledgements/Approvals (i.e. Annual Progress Reports etc)	NA	4	
Ethics Committee Roster/Membership List or Compliance Statement	NA	4	
Expedited Pregnancy Report Forms - Initial and Follow Up	NA	4	
Expedited Safety (SAE) Report Form - Initial and Follow Up	NA	4	
Expedited Safety (SAE) Report Review Form	NA	4	
International Regulatory Submissions & Approvals - Initial Application	NA	4	
International Regulatory Submissions & Approvals - Subsequent Applications	NA	4	
Investigational Brochure Version Tracker – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Investigational Drug Log - Bulk and Individual	NA	4	- Not required - Filed outside of Florence until the end of the study
Investigational Product/Device Log – Site Specific	NA	4	- Not required - Filed outside of Florence until the end of the study
Laboratory Reference Ranges / Lab Normals	NA	4	
Medical Device Annual Reports, if applicable	NA	4	
Medical Licenses	NA	4	
Monitoring Correspondence	NA	4	
NATA Accreditation Certificate/CLIA/CAP	NA	4	
Newsletters	NA	4	
Non-Compliance Report Forms	NA	4	

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

Document	Signature Type *(Addendum, Stamp, Form, or N/A)*	Work Flow	Notes
Non-Compliance Report Review Forms	NA	4	
Non-Compliance Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Participant ID Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
PICF Version Tracker – Site Specific	eLog	4	
Pre Screening Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Protocol Version Tracker	eLog	4	- Florence eLog
Recruitment Material	NA	4	
SAE / URSAE / SUSAR Line Listings	NA	4	
RGO Submission & Approval – Initial Application	NA	4	
RGO Submission & Approval – Subsequent Applications	NA	4	
SAE / URSAE / SUSAR Line Listings	NA	4	
Screening Log – Site Specific	Form eLog	4	- Import writable form; or - Florence eLog
Serious Breaches & Suspected Serious Breaches Report Form	NA	4	- Completed via the ERM for Australian Sites
Site Initiation Attendance Log	Wet ink	4	
Site Randomisation List / Registration List	Form eLog	4	- Import writable form; or - Florence eLog
Sponsor Correspondence	NA	4	
Staff Licenses – AHPRA	NA	4	
Staff Training (Protocol and Amendment Training)	NA	4	
Staff Training Certificates (GCP, EDC, HIPAA, etc)	NA	4	
Wet-Ink Signature Log	Wet ink	4	

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