eTMF 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 Monitoring Plan Approval & Sign-Off	Stamp Form	Approval	2 3	- CPI - Trial Coordinator - Monitor (if applicable)	- Stamp Approval can be applied directly to the Clinical Monitoring Plan - Import writable form if using a separate Approval Form
Clinical Trial Research Agreement	Form	Acknowledge	3	- MCRI COO (alert PA) - Participating Site Authorised Representative (if applicable) - Participating Site PI	- Import writable form - Note, not all CTRAs may be able to be executed/ signed via Florence
CRO Vendor Assessments	Form	Approval	3	- CPI - Trial Coordinator - Monitor (if applicable)	- Import Writable Form
Data Sharing Plan	Form	Approval	3	- CPI	- Import Writable Form
Database Approval Form	Form	Approval	3	- CPI - Database Manager - Statistician - Trial Coordinator	- Import Writable Form
Delegation of Authority Log – Central Team	Form eLog	Non-PI: Acknowledge PI: Approval	3	All members from the Central Trial Coordinating Team involved within the study	- Import Writable Form; or - Florence eLog
DSMB Charter Approval & Sign-Off	Stamp Form	Approval	2 3	All DSMB Committee Members	- Stamp Approval can be applied directly to DSMB Charter - Import writable form if using a separate Approval Form
FDA 1572 Form	Form	Approval	3	- CPI - All listed CI's	- 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 – Sponsor Acknowledged	Stamp	Acknowledge	2	- Sponsor Representative - CPI	
Investigator Agreement to Archive – Sponsor Acknowledged	Form	Acknowledge	3	- CPI	- Import Writable Form
Non-Compliance Report Review Form	Form	CPI/Delegate: Acknowledge Site PI: Acknowledge	3	- CPI - Site PI	- Import Writable Form
Other Agreements (i.e. MTAs/Data Sharing Agreements etc)	Form	Acknowledge	3	- MCRI COO (alert PA) - MCRI Legal - Others, as required	- Import Writable Form - Not all Agreements may be able to be executed/signed via Florence
PICF Approval & Sign-Off Form	Form	Approval	3	- CPI - Trial Coordinators - PICF Author (if applicable)	- Import Writable Form
Principal Investigator Declaration Form	Form	Acknowledge	3	- CPI	- Import Writable Form

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*
Protocol	Stamp Form	Authorship	3	- CPI or Sponsor Representative	- Import Writable Form, if not requesting Stamp signature
Protocol Approval & Sign-Off Form	Form	Approval	3	- CPI - Trial Coordinators - Statistician - Protocol Authors (if applicable)	- Import Writable Form
Research Sample Laboratory Manual Approval & Sign-Off	Stamp Form	CPI: Approval Research Lead: Authorship/ Acknowledge	2 3	- CPI - Research Sub-Study Lead	- Stamp Approval can be applied directly to the Lab Manual - Import writable form if using a separate Approval Form
Roles & Responsibilities Matrix	Form	Acknowledge	3	- CPI - Sponsor Representative	- Import Writable Form
Statistical Analysis Plan (SAP) Approval & Sign-Off	Stamp Form	Approval	2 3	- CPI - Statistician	- Stamp Approval can be applied directly to the SAP - Import writable form if using a separate Approval Form
Secondary Label Approval Form	Form	Approval	3	- Sponsor Representative; or - CPI	- Import Writable Form
Site Feasibility Assessments	Form	Approval	3	- CPI - Trial Coordinator - Team Coordinator - Team Member	- Import Writable Form
Site Green Light Approval Form	Form	Authorship	3	- Trial Coordinator	- Import Writable Form
Staff CVs	Stamp	Approval	2	All members from the Central Trial Coordinating Team involved within the study	
Training Log – Central Team	Form eLog	Non-PI: Acknowledge CPI: Approval	3	All members from the Central Trial Coordinating Team involved within the study	- Import Writable Form; or - Florence eLog
Trial Steering Committee Charter & Sign Off	Stamp Form	Approval	2 3	- All Trial Steering Committee Members	- Stamp Approval can be applied directly to the TSC Charter - Import writable form if using a separate Approval Form

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 eTMF

Document	Signature Type *(Addendum, Stamp, Form, or N/A)*	Work Flow	Notes
Annual Safety Reports	NA	4	- Completed via the ERM for Australian Sites
CAPA Tracking Log – Master	Form eLog	4	- Import writable form; or - Florence eLog
Database Version Tracker	Form eLog	4	- Import writable form; or - Florence eLog
DSMB Reports	NA	4	- For blinded studies, closed DSMB reports be filed outside of Florence until the end of the study.
DSUR	NA	4	
Enrolment Log – Master	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 Form – Master	NA	4	
Expedited Safety (SAE) Report Form – Master	NA	4	
Expedited Safety (SAE) Report Review Form – Master	NA	4	
IB or Package Inserts (Primary Label)	NA	4	
International Regulatory Submissions & Approvals - Initial Application	NA	4	
International Regulatory Submissions & Approvals - Subsequent Applications	NA	4	
Investigational Brochure Version Tracker	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	NA	4	- Not required - Filed outside of Florence until the end of the study
MCRI Sponsorship Committee Approval Letter	NA	4	
Medical Device Annual Reports, if applicable	NA	4	
Medical Licenses	NA	4	
Monitoring Close Out Report – Master	Form	4	
Monitoring Correspondence	NA	4	
NATA Accreditation Certificate/CLIA/CAP	NA	4	

Study Documents not Requiring Signature Workflows within the eTMF cont'd

Document	Signature Type *(Addendum, Stamp, Form, or N/A)*	Work Flow	Notes
Newsletters	NA	4	
Participant ID Log – Master	Form eLog	4	- Import writable form; or - Florence eLog
PICF Version Tracker – Master	eLog	4	
Pre Screening Log – Master	Form eLog	4	- Import writable form; or - Florence eLog
Protocol Deviation Form / Non-Compliance Report Form	NA	4	
Protocol Deviation Form / Non-Compliance Review Form	NA	4	
Protocol Deviation Log / Non-Compliance Log (Major Deviations) – Master	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	
Screening Log – Master	Form eLog	4	- Import writable form; or - Florence eLog
Serious Breaches & Suspected Serious Report Form	NA	4	- Completed via the ERM for Australian Sites
Signature Log	Wet ink	4	
Site Monitoring Visit Log – Master	Form eLog	4	- Import writable form; or - Florence eLog
Source Document Plan – Master	Form	4	- Import writable form; or
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	
Study Vendor Log	Form eLog	4	- Import writable form; or - Florence eLog
Unblinding Log	Form	4	- Import writable form