Florence™ Electronic Workflows & eSignature Reference Guide

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 Florence 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

eLogs

VISIBLE Signatures **ON** selected log row

(Delegation of Authority Logs, Site Visit Logs)

eLog Signature Request Process:

1. Click on "Actions" to the far right of your row, select "Request Signatures"
2. Select Potential Signers(s), appropriate signature column, 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 5

No signature required

Simply upload document. No signature actions required.

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
1.0 Study Subject Information				
1.1 Individual Subject Folders				
RENAME Study ID (Initials)				
Subject Visit Log	e-Log	Responsibility	4	P
Information Sheet	N/A	N/A	5	
Signed Informed Consent(s) or Assent(s)	Wet-Ink	N/A	Other	
HIPAA Authorization				
Blank HIPAA Authorization	Wet-Ink	N/A	Other	
Used HIPAA Authorizations	N/A	N/A	5	
Screening and Eligibility Worksheets with Documentation	Wet-Ink	N/A	Other	
Visit Worksheets with Documentation				
Pending Visits	Wet-Ink	N/A	Other	
Previously Completed Visits	N/A	N/A	5	
Adverse Events				
Subject Adverse Event Log	e-Log	Approval	4	p
Adverse Event Documentation	N/A	N/A	5	
Protocol Deviations				
Subject Protocol Deviation Log	e-Log	Approval	4	P
Protocol Deviation Documentation	N/A	N/A	5	
Counseling by Site	N/A	N/A	5	
1.2 Logs				
Study Visit Log	Stamp	Acknowledge	2	
Enrollment Log	Stamp	Approval	2	
Screening Visit Log	Stamp	Acknowledge	2	P
Subject ID Code List	e-Log	Responsibility	4	P
Master Subject Log	e-Log	Approval	4	P

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
1.3 Equipment Assigned to Subject	e-Log	Responsibility	4	P
1.4 Decoding Procedures	N/A	N/A	5	
1.5 Example Source Worksheets	N/A	N/A	5	
2.0 IRB and Safety Committee Reviews				
2.1 Initial IRB Protocol Submission				
IRB Approval	N/A	N/A	5	
IRB Modification Requests	N/A	N/A	5	
Final Smartform	N/A	N/A	5	
Informed Consent or Assent				
Final Consent(s) or Assent(s) Version	N/A	N/A	5	
Drafts or Working Versions for Submission	N/A	N/A	5	
ICH E6 Worksheet	N/A	N/A	5	
IRB Correspondence	N/A	N/A	5	
IRB Roster at Date of Initial & Final Review	N/A	N/A	5	
Notification of Approval				
OCRICC	N/A	N/A	5	
Other Affiliate	N/A	N/A	5	
Sponsor	N/A	N/A	5	
Affiliate Correspondence	N/A	N/A	5	
Sponsor Correspondence	N/A	N/A	5	
2.2 Protocol Amendments				
RENAME Administrative 0001				
IRB Approval	N/A	N/A	5	
Smartform Change Request	N/A	N/A	5	
RENAME AME00012345 Short-Title of Amendment				
IRB Approval	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
2.2 Protocol Amendments Continued				
Informed Consent or Assent				
Final Consent(s) or Assent(s) Version	N/A	N/A	5	
Drafts or Working Versions for Submission	N/A	N/A	5	
IRB Modification Requests	N/A	N/A	5	P
Final Smartform	N/A	N/A	5	
IRB Correspondence	N/A	N/A	5	
Notification of Change or Training to Study Team	Stamp	Acknowledge	2	P
Notification of Approval				
OCRICC	N/A	N/A	5	
Other Affiliate	N/A	N/A	5	
Sponsor	N/A	N/A	5	
Affiliate Correspondence	N/A	N/A	5	
Sponsor Correspondence	N/A	N/A	5	
2.3 Continuing Progress Reports				
RENAME CPR00012345 YYYY-YYYY				
IRB Approval	N/A	N/A	5	
Informed Consent or Assent				
Final Consent(s) or Assent(s) Version	N/A	N/A	5	
Drafts or Working Versions for Submission	N/A	N/A	5	
IRB Modification Requests	N/A	N/A	5	
Final Smartform	N/A	N/A	5	
IRB Correspondence	N/A	N/A	5	
IRB Roster	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
2.3 Continuing Progress Reports Continued				
Notification of Approval				
OCRICC	N/A	N/A	5	
Sponsored Programs	N/A	N/A	5	
Other Affiliate	N/A	N/A	5	
Sponsor	N/A	N/A	5	
Affiliate Correspondence	N/A	N/A	5	
Sponsor Correspondence	N/A	N/A	5	
2.4 Reportable Events				
RENAME RE0000XXXX Title of RE				
IRB Acknowledgement	N/A	N/A	5	
IRB Modification Requests	N/A	N/A	5	
Final Smartform	N/A	N/A	5	
IRB Correspondence	N/A	N/A	5	
Notification of Change or Training to Study Team	Stamp	Acknowledge	2	P
Notice of Event				
OCRICC	N/A	N/A	5	
Other Affiliate	N/A	N/A	5	
Sponsor	N/A	N/A	5	
Affiliate Correspondence	N/A	N/A	5	
Sponsor Correspondence	N/A	N/A	5	
2.5 MCW QA-QI Reviews and Audits				
Notice of Review or Audit	Stamp	Acknowledge	2	
Summary of Findings	N/A	N/A	5	
Corrective Action Plan	Form	Approval	3	P
Correspondence	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
2.6 Safety Committee Submissions				
2.7 Study Closure Notifications				
IRB	N/A	N/A	5	
Safety Committee's	N/A	N/A	5	
3.0 External Monitoring and Auditing				
3.1 Site Initiation Visit				
SIV Confirmation Letter	N/A	N/A	5	
SIV Follow-up Report	Stamp	Acknowledge	2	
SIV Correspondence	N/A	N/A	5	
3.2 Interim Monitoring Visits				
IMV Confirmation Letter	N/A	N/A	5	
IMV Follow-up Report	Stamp	Acknowledge	2	
IMV Correspondence	N/A	N/A	5	
3.3 Closeout				
Confirmation Letter	N/A	N/A	5	
Follow-up Report	Stamp	Acknowledge	2	
Correspondence	N/A	N/A	5	
3.4 Monitor Visit Log	e-Log	Approval	4	P
3.5 Sponsor Auditor Visits				
Compliance Notification Letter	N/A	N/A	5	
Follow-up Report	Stamp	Acknowledge	2	
Correspondence	N/A	N/A	5	
3.6 Regulatory Auditor Visits				
Regulatory Audits Notice of Inspection	Stamp	Acknowledge	2	
Copy of All Documentation Provided to Auditor	N/A	N/A	5	
Inspection Report	Stamp	Acknowledge	2	
Site Response to Inspection Report	N/A	N/A	5	
Correspondence	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
4.0 Sponsor Documents				
4.1 Protocols				
Sponsor Protocol	Addendum	Review	1	
Redline Version	N/A	N/A	5	
Signature Page	Form	Acknowledge	3	
4.2 Investigator Brochure				
Investigator Brochure	Addendum	Review	1	
Acknowledgement Receipt	Form	Acknowledge	3	
Redline Version	N/A	N/A	5	
4.3 Informed Consent or Assent				
IRB Approved Consent(s) or Assent(s)	N/A	N/A	5	
Consent Translations with Translation Certificates	N/A	N/A	5	
4.4 Subject Facing Materials				
Questionnaires	N/A	N/A	5	
Copyright Certificates	N/A	N/A	5	
Instructional Materials	N/A	N/A	5	
Diaries	N/A	N/A	5	
Advertisements	N/A	N/A	5	
4.5 Safety Reports				
Data Safety Monitor Board Charter	N/A	N/A	5	
DSMB Reports	Addendum	Acknowledge	1	
External Safety Reports				
Safety Report Log	e-Log	Responsibility	4	P
Safety Report(s)	Form	Approval	3	P
Notification to Investigators of Safety Information	Addendum	Acknowledge	1	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
4.6 Sample Case Report Forms	N/A	N/A	5	
4.7 Operations Manuals				
Interactive Response Technology (IVRS, IWRS)	N/A	N/A	5	
Data Management Systems	N/A	N/A	5	
Central Laboratory Documents	N/A	N/A	5	
Core Lab Documents	N/A	N/A	5	
Study Shipping and Supply Accountability	N/A	N/A	5	
4.8 MCW Equipment Maintenance Records				
Biomedical Evaluation of Sponsor Provided Equipment	N/A	N/A	5	
Calibration Records	N/A	N/A	5	
Temperature Log Maintenance	N/A	N/A	5	
4.9 Local Laboratory Documents				
Lab Manual	N/A	N/A	5	
Lab Normal Reference Ranges	N/A	N/A	5	
Lab Sample Storage Condition Log	N/A	N/A	5	
Retained Samples Log	N/A	N/A	5	
Lab Shipment Records	N/A	N/A	5	
CLIA	N/A	N/A	5	
CAP	N/A	N/A	5	
4.10 Pharmacy				
Pharmacy Manual	N/A	N/A	5	
Closeout Documents	N/A	N/A	5	
5.0 Communications				
5.1 Site Generated				
Team Correspondence	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
5.2 Sponsor Generated				
Investigator or Study Newsletters	N/A	N/A	5	
Clinical Study Report	Stamp	Acknowledge	2	
6.0 General Regulatory and Personnel Management				
6.1 Contacts				
Site Contact Details	N/A	N/A	5	P
Sponsor Contact Details	N/A	N/A	5	
6.2 Regulatory Documents				
Delegation of Authority Log	e-Log	PI:Approval Non-PI: Acknowledge	4	P
Site Signature Log	Wet-Ink	N/A	Other	
FDA 1572	Form	Approval	3	P
Fully Executed Investigator Agreement	N/A	N/A	5	
Fully Executed Sub-Investigator Agreements	N/A	N/A	5	
Investigator Regulatory Agreement	N/A	N/A	5	
Financial Disclosure Forms	Form	Approval	3	
6.3 Notes to File				
Sponsor Memos to File	N/A	N/A	5	
Site Notes to File	Form	Approval	3	
6.4 Staff Qualifications & Training				
Study Related Training	Addendum	Acknowledge	1	
Affiliate Staff Training	Addendum	Acknowledge	1	
PI Credentialing	N/A	N/A	MCW Central Binder	Shortcut
Sub-Investigator Credentialing	N/A	N/A	MCW Central Binder	Shortcut
Study Staff Credentialing	N/A	N/A	MCW Central Binder	Shortcut
7.0 Feasibility and Qualification				
7.1 Interest and Feasibility				
Site Interest Notification	Stamp	Review	2	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
7.2 Disclosure Agreements				
Fully Executed Confidentiality or Non-Disclosure Agreement(s)	N/A	N/A	5	
Draft Confidentiality or Non-Disclosure Agreement(s)	N/A	N/A	5	
Feasibility Questionnaire and Supportive Documents	N/A	N/A	5	
MCW Research Standard Operation Procedures and Processes	N/A	N/A	MCW Central Binder	Shortcut
Facility Standards (EPIC, Part 11 Compliance, etc.)	N/A	N/A	MCW Central Binder	Shortcut
7.3 Qualification Notification	Stamp	Acknowledge	2	
7.4 Initiation Planning for Project	N/A	N/A	5	
8.0 Contracts and Financials				
8.1 Investigator Agreements				
Clinical Trial Agreements				
Fully Executed Clinical Trial Agreement(s)	N/A	N/A	GCO	
Draft(s) Clinical Trial Agreement(s)	N/A	N/A	GCO	
Insurance Documentation	N/A	N/A	5	
Data Privacy Use Agreement	N/A	N/A	GCO	
Vendor & Site Communications	N/A	N/A	5	
8.2 Third Party Contracts (External)				
Vendor Contracts	N/A	N/A	GCO	
Communications	N/A	N/A	5	
8.3 Pricing - Budgeting Components (Internal)				
OCRICC	N/A	N/A	5	
MCW CPS	N/A	N/A	5	
Radiology	N/A	N/A	5	

Document	Signature Type *(Addendum, Stamp, Form, eLog, N/A or Wet-Ink)*	Signature Reason *(Acknowledge, Approval, Authorship, Responsibility, or Review)*	Workflow *See p.1 for detailed steps*	Central Binder *Create & Maintain Document for Study Team use*
8.3 Pricing - Budgeting Components (Internal) Continued				
Wisconsin Diagnostic Laboratories	N/A	N/A	5	
Opthalmology	N/A	N/A	5	
CTSI	N/A	N/A	5	
MCW ATRU	N/A	N/A	5	
MCW External Departments	N/A	N/A	5	
Investigational Drug Service	N/A	N/A	5	
Cell Therapy Lab	N/A	N/A	5	
8.4 Coverage Analysis				
OCRICC	N/A	N/A	5	
Guidestar	N/A	N/A	5	
MCW CPS	N/A	N/A	5	
8.5 Medicare Submission				
8.6 Financial Documentation				
Clinical Trial Budget or Grant				
Final Budget or Grant	N/A	N/A	GCO	
Drafts Budget(s) or Grant(s)	N/A	N/A	GCO	
Justifications used for Budget Negotiation	N/A	N/A	5	
Subject Reimbursement Tracking	e-Log	Responsibility	4	P
Sponsored Programs Notification of Account Activation	N/A	N/A	5	
Billing (Invoices)	N/A	N/A	5	
Credits (Checks)	N/A	N/A	5	
8.7 Internal Closeout Procedures				
Internal and Affiliate Partner Notifications	N/A	N/A	5	
Account Reconciliation and Closure	N/A	N/A	5	P
GCO Closure Notification	N/A	N/A	5	

Florence eBinders Signature Reasons and Explanations-

Reason	Explanation
Acknowledge	The person signing has read, understands, and agrees to abide by the consequences
Approval	The person signing approves the document's content
Authorship	The person signing is the author of the document
Responsibility	The person signing takes responsibility for the document's content
Review	The person signing has reviewed the document's content