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:

- Select Manage "Request Signature"
- On the Documents tab, choose Addendum as Signature Type and the Signature Reason. Click the Signers tab and search for the signer(s) for the document. If desired, select "Sign by Date". Check "Notify Me" to be notified upon signing and "Email Signer" to send email notification to requested signer (Recommended)
- Add comments to signer(s) if desired.
- Click "SAVE"

Workflow 2

STAMP Signatures

VISIBLE Signature **ON** Documents Required (Non-forms , such as CVs)

eSignature Request Process:

- Select Manage "Request Signature"
- On the Documents tab, choose Stamp as Signature Type and the Signature Reason. Click the Signers tab and search for the signer(s) for the document. If desired, select "Sign by Date". Check "Notify Me" to be notified upon signing and "Email Signer" to send email notification to requested signer (Recommended)
- Add comments to signer(s) if desired.
- 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:

- Upload approved Form. Confirm the form displays correctly in Florence and eSignature box is yellow.
- 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:

- Select Manage "Request Signature"
- On the Documents tab, choose the Signature Reason (signature type will populate by default). Click the Signers tab and search for the signer(s) for the document. If desired, select "Sign by Date". Check "Notify Me" to be notified upon signing and "Email Signer" to send email notification to requested signer (Recommended).
- 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:

- Click on "Actions" to the far right of your row, select "Request Signatures"
- On the Signers tab, search for signer(s) and select the Column for their signature and Reason. If desired, select "Sign by Date". appropriate signature column, signature reason, and Sign By Date if desired. Check "Notify Me" to be notified upon signing and "Email Signer" to send email notification to requested signer (Recommended).
- Add comments to signer(s) if desired.
- Click "SAVE"

Document	Signature Type *(Recommended)*	Signature Reason *(Recommended)*	Workflow *See p.1*
1572	Form	Approval	3
Adverse Events	eLog	Approval	4
Consent Form	Form	Approval	3
Continuing Review	Addendum	Acknowledge	1
Delegation of Authority Log	eLog	Authorship	4
Device Annual Reports	Stamp	Acknowledge	2
DSMC Reports	Addendum	Acknowledge	1
Eligibility/Enrollment Forms	Stamp	Approval	2
Enrollment Log	eLog	Acknowledge	4
Financial Disclosure (sponsor provided)	Form	Approval	3
IB or Package Inserts	Addendum	Acknowledge	1
IB Receipt Page	Form	Acknowledge	3
ICF Version Log	eLog	Acknowledge	4
Initial Submission	Addendum	Acknowledge	1
INDSRs	Addendum	Review	1
Investigational Drug Log	eLog	Approval	4
Investigational Product/Device Log	eLog	Approval	4
IRB Approvals	Addendum	Acknowledge	1
Monitoring Correspondence	Stamp	Acknowledge	2
Monitoring Close Out Report	Stamp	Acknowledge	2
NTF	Form	Acknowledge	3

Document	Signature Type *(Recommended)*	Signature Reason *(Recommended)*	Workflow *See p.1*
Physician Agreement Page	Form	Approval	3
Protocol	Addendum	Acknowledge	1
Protocol Agreement/Signature Page	Form	Acknowledge	3
Protocol Deviation Form	Form	Acknowledge	3
Protocol Deviation Log	eLog	Acknowledge	4
Protocol Signature Page	Form	Acknowledge	3
Recruitment Material	Addendum	Acknowledge	1
SAE	Stamp	Approval	2
Screening Log	eLog	Acknowledge	4
Signature Log	eLog	Acknowledge	4
Site Visit Log	eLog	Acknowledge	4
Sponsor Correspondence	Addendum	Acknowledge	1
Staff CVs	Stamp	Authorship	2
Sponsor Site Visit Log	eLog	Acknowledge	4
Staff Training (Protocol and Amendment Training)	eLog	Acknowledge	4
Patient ID Log	eLog	Acknowledge	4