Signing Documents and Logs in eBinders Bruce Steinert, PhD, CCRA

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Electronic Signatures

- Equivalent of handwritten signature
- Available on multiple devices (computer, tablet, phone)
- Available from any location with internet access



Signature Types

- Addendum signature
 - Does not appear on the document but can be downloaded
 - Used to document training (protocol, IB, etc.), certify copies of uploaded documents
- Stamp signature
 - Appears on the document
 - Used for logs, FDA forms, financial disclosures, protocol/IB receipt forms, CVs, etc.



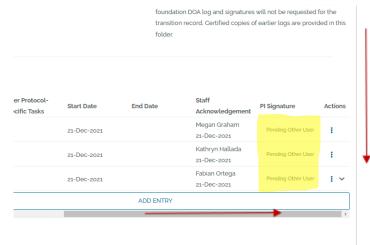
What to Sign?

- Scheduled notification
 - Email from Florence system (florence@researchbinders.com)
 - Can be coordinated to administrative day
- Emailed notification
 - Email from requester (via Florence system)
 - Used for time-sensitive communications
- Tips -
 - Don't change the 'Reason for Signing' field
 - If a 'Date' field is included, a typed date is required (e.g., FDA forms)
 - Click 'Yes Keep Signing' to complete all documents in your queue



How to Sign – Delegation Log (PI)

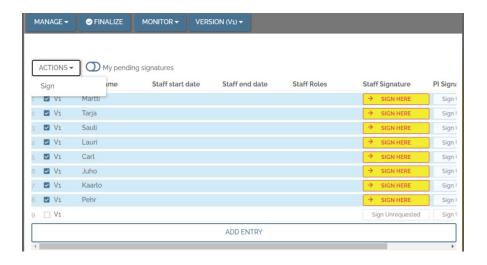
- Field to sign might not be immediately visible
- Scroll to bottom of log, then to the right to see the PI signature column





DOA Log - Batch Signing

- PI can sign up to 10 log rows with one action
- Select rows by checking box to left of row; select 'Sign' on 'Actions' menu





DOA Log - Sign

Enter PIN and Save

Save Row Signatures January Log

CS Team / ■ TEsting / eLogs / ■ January Log

I, elina.huttunen@florencehc.com, am authorizing 8 row signatures. By signing, I am verifying that I have reviewed all selected data and understand this bulk signature is the legally binding equivalent of an individual electronic signature:

Row	Column	Reason	
1	Staff Signature	Review	٠
2	Staff Signature	Authorship	ı
3	Staff Signature	Authorship	
4	Staff Signature	Acknowledge	

*Password



* Required by 21 CFR Part 11





How to Sign – FDA Forms

Add date of signing, then complete signing process

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO incorporate this information along with other technical data into an Investigational New Drug SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

Click to sign

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per Departing the time to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and the fine to review instructions, search existing data sources, gather and fine for the fine to review instructions, search existing data sources, gather and fine for the fine for this collection of information is estimated to average 100 hours per Departing the fine for this collection of information is estimated to average 100 hours per Departing the fine for this collection of information is estimated to average 100 hours per Departing the fine for this collection of information is estimated to average 100 hours per Departing the fine for this collection of information is estimated to average 100 hours per Departing the fine for the fin



How to Sign -Forms

- Enter any data and check appropriate boxes, then click to sign
- Might need to scroll vertically to access all responses
- Examples
 - Financial Disclosure Forms (text, check boxes)
 - Feasibility Tools (text, check boxes)
 - Protocol and IB acknowledgement forms



How to Sign – Addendum Signature

- Addendum signatures do not appear on the document
- No yellow highlighted field
- Click 'Sign' and follow instructions





Declining a Signature

- When to decline?
 - Document sent in error (wrong signer)
 - Inaccurate information on document
- Click 'Decline' and enter reason for declining.
- Click 'Decline' button
- Requester will be informed of declined signature



Questions or Problems

- Contact Bruce Steinert (<u>bsteinert@mcw.edu</u>) or Marc Casati (<u>mcasati@mcw.edu</u>)
- Florence Help Desk (<u>Florence@mcw.edu</u>)

