Standard Operating Procedure

Recording And Signing An Experiment Entry In The Electronic Laboratory Notebook

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Version	1.0
Effective date	[Date]
Owner	[Laboratory Operations]
Review cycle	Every two years, or sooner if the ELN or a regulation changes

1. Purpose

This procedure sets out how laboratory staff record experiment data in the electronic laboratory notebook (ELN) and sign their entries. Records kept this way meet the organisation's data integrity policy and the requirements of 21 CFR Part 11 for electronic records and signatures.

2. Scope

It applies to every person who creates, reviews or witnesses experiment entries in [ELN system] at [site]. It doesn't cover setting up instrument integrations or administering the ELN.

3. Responsibilities

- **Author -** Records data at the time of the work and signs the entry as author.
- **Reviewer -** Checks the entry for completeness and accuracy, and signs it as reviewed. The reviewer can't be the author.
- **Laboratory manager -** Makes sure staff are trained before they use the ELN, and resolves any deviation raised during review.
- **ELN administrator -** Manages user accounts and makes sure audit trails are retained.

4. Definitions

- **ALCOA+ -** Data integrity principles. Records must be attributable, legible, contemporaneous, original and accurate, as well as complete, consistent, enduring and available.
- **Audit trail -** A secure, computer-generated, time-stamped record of who created, changed or signed an entry, and when.
- **Electronic signature -** A signature applied in the ELN by re-entering a user ID and password. It records the signer's name, the date and time, and what the signature means.

5. Procedure

5.1 Create the entry

1. Log in with your own user ID and password. Never share credentials or work under another person's login.
2. Open the correct project and create a new entry from the approved template.
3. Title the entry with the experiment ID from [the study plan].

5.2 Record the data

1. Record observations as the work happens, not afterwards.
2. Attach raw data files exported directly from the instrument. Don't retype values that the instrument already recorded.
3. Record units with every value.
4. If the work departs from the method, describe the deviation in the entry before you sign it.

5.3 Correct an entry

1. Never delete data. Use the ELN's amend function.
2. Enter a reason for every change.
3. The original value stays visible in the audit trail.

5.4 Sign as author

1. Complete all required fields in the template.
2. Select Sign, re-enter your user ID and password, and choose Author as the signature meaning.
3. The ELN records your name, the date and time, and the signature meaning on the entry.

5.5 Review the entry

1. Within [number] working days, the reviewer checks that the data is complete, that attachments open and that calculations are correct.
2. If anything needs to change, the reviewer returns the entry to the author with comments.
3. When the entry is correct, the reviewer signs it with the meaning Reviewed.

5.6 Lock the entry

After the review signature, the entry locks. Any later change needs an amendment, a reason and new signatures from the author and the reviewer.

6. Records

Signed entries and their audit trails are kept for [retention period] under [records retention policy].

7. References

- 21 CFR Part 11, Electronic Records; Electronic Signatures
- [Data Integrity Policy]
- [ELN User Guide]

8. Revision History

Version	Date	Change	Author
1.0	[Date]	First issue	[Name]

9. Approval

Role	Name	Signature	Date
Prepared by	[Name]		
Reviewed by	[Name]		
Approved by	[Quality Assurance]		