QUICK GUIDANCE

# Correcting Errors in Source Documents

THE UNIVERSITY OF ARIZONA Research & Partnerships

***How to correct inaccurate entries in paper and electronic records***

## WHAT IS IT?

> **Source Document Error:**
>
> Any inaccurate, incomplete, or incorrectly recorded entry in a clinical trial record. Errors must be corrected using a transparent, GCP-compliant method that preserves the original entry.

## WHEN DOES THIS APPLY?

- An incorrect value, date, or entry is identified in a paper source document
- A transcription error is found between source and EDC data
- A monitor or auditor identifies an erroneous entry
- A staff member records information in the wrong subject file

## PROCESS AT A GLANCE

### 1. Identify the Error

- Confirm the entry is incorrect by cross-referencing other source documents, lab reports, or the EDC
- Do not attempt to correct the record until you are certain of the correct information
- Notify the PI if the error may have affected subject safety or data integrity

### 2. Correct Paper Source Documents

- Draw a single line through the incorrect entry — do not use correction fluid (white-out) or cover the original
- Write the correct information adjacent to or above the original entry
- Initial and date the correction, and add a brief reason if it is not obvious (e.g., 'transcription error', 'wrong subject file')

### 3. Correct Electronic Source Documents

- Follow your site's and the system's audit trail procedures
- Enter the correction with the current date — do not alter the original timestamp
- Provide a reason for the change in the audit trail comment field

### 4. Correct EDC Data (if applicable)

- Respond to monitor or system queries with the correct information and a clear explanation
- Ensure the EDC audit trail reflects the change, who made it, and when

### 5. Notify the PI and Document

- Inform the PI of any corrections that could affect safety data or primary endpoints
- Create a note-to-file if the correction is significant or systemic
- Retain the original document — never destroy it

### 6. Determine if a Protocol Deviation is Required

- Assess whether the error reflects a deviation from protocol procedures
- If so, initiate a Protocol Deviation report Reportable New Information
- Implement preventive actions to reduce recurrence

## KEEP IN MIND

**x Avoid:** Never use white-out, correction tape, or any method that obscures the original entry. Never backdate corrections or alter records to conceal an error.

✓ **Best practice:** Always preserve the original entry. Make corrections transparently with initials, date, and reason. When in doubt, ask the PI or sponsor monitor.

## REFERENCES


- ICH E6(R2) Good Clinical Practice Guidelines
- Reportable New Information https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf
- Applicable EDC User Manual