



SOP #	
Author	
Approver	
Version #	
Version Date	
Effective Date	

Standard Operating Procedure
Correcting Research Records

1 Purpose:

- 1.1 In order to maintain accurate and complete records, there is an occasional requirement for a correction to be made to the research record. This SOP describes the process for making corrections to data entered in research documents.
- 1.2 The process begins when an error is identified.
- 1.3 The process ends when the corrected entry has been signed and dated.

2 Revisions from Previous Version:

- 2.1 None

3 Policy:

- 3.1 Errors in research records will be corrected in a transparent manner, in accordance with ICH E6 Good Clinical Practice (GCP).
 - 3.1.1 The original entry will not be obscured, allowing it to be legible; the use of white-out, scribbles, or other marks to obscure the original entry are not allowed.
- 3.2 All corrections and clarifying explanations (as appropriate) will include the signature and date of the person making the entry, as to allow the changes to be traceable.

4 Responsibilities:

- 4.1 All study personnel

5 Procedure:

- 5.1 Identify an incorrect entry
- 5.2 Make the correction using the following steps
 - 5.2.1 Strike through the original entry with one single line
 - 5.2.2 Enter the correct data
 - 5.2.2.1 Include an explanation of the change, as applicable
- 5.3 Person making the correction signs and dates the entry

6 Materials:

- 6.1 None

7 References:

- 7.1 International Conference on Harmonization, Guideline for Good Clinical Practice

8 Revision History:

Revision	Date	Description of Changes	Revised By
0.0	mm-dd-yy	Initial release	