**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:**

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