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Document History			
Effective Date: (YYYY-MM-DD)	DCR:	Revision:	Description / Change
		1	Initial Release

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1. PURPOSE

- 1.1 This procedure defines the practices to be followed when completing InnovaBio® research records.

2. SCOPE

- 2.1 This procedure is applicable to records at InnovaBio®, including those maintained by the Manufacturing, Quality Assurance, Validation, and Research & Development departments.

3. RESPONSIBILITIES

- 3.1 It is the responsibility of all interns to adhere to the good documentation practice requirements described in this procedure.

4. REFERENCES

- 4.1 21 CFR 820.180, Records, General Requirements
- 4.2 21 CFR 211.180 Records and Reports General Requirements

5. DEFINITIONS

- 5.1 Data transcription – To write out an exact copy of original data
- 5.2 Permanent Ink – Ink that is not water soluble or erasable
- 5.3 Quality System Records – Those records required by the Code of Federal Regulations, Title 21, Part 210, Part 211, and Part 820, including training records, manufacturing records, laboratory controls, etc.
- 5.4 Reproducible ink - Ink that is discernable when the original is photocopied

6. PROCEDURE

6.1 Accurate Record Keeping

- 6.1.1 Accurate records ensure that activities are documented, including what occurred, and when it occurred. The FDA considers that if an activity is not documented, it did not happen.
- 6.1.2 Mistakes in paperwork are to be corrected immediately upon detection.
- 6.1.3 Written records must be presentable to the FDA.

6.2 Record Keeping Requirements

- 6.2.1 Use permanent, reproducible blue ink. Do not use pencil.

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- 6.2.2 Write legible and clearly, so that the information may not be interpreted incorrectly. Do not rush through the recording activity.
- 6.2.3 Sign and date tasks immediately upon completion.
- 6.2.4 Do not leave blanks in the record.
- 6.2.5 N/A any unused lines. Line through once, write “N/A”, initial and date.
- 6.2.6 Do not use ditto marks. Enter any repetitive data individually.
- 6.2.7 Enter only known information. Do not guess on any written entry.
- 6.2.8 Include enough details so that the record can be understood in the future.
- 6.2.9 Do not document the work of another employee.
- 6.2.10 Document nonconformities and deviations.
- 6.2.11 As applicable, document all materials used.
- 6.2.12 Do not pre-date or post-date any documented information. Always use the current date. There are no exceptions to this requirement.
- 6.2.13 The date format is to be written as Day Abbreviated Month Year (04 Aug 2014).
- 6.2.14 Do not use Post-itTM notes, napkins, notepad paper or other unapproved notes to document information.
- 6.2.15 Use proper error correction methods.

6.3 Error Correction Requirements

- 6.3.1 Use permanent, reproducible blue ink. Do not use pencil.
- 6.3.2 Do not attempt to erase an error. Do not use correction fluid or tape, also known as “white-out”.
- 6.3.3 Make a single line through the error. Do not “scribble” out or make more than one line through the error. The original data must be readable and/or visible.
- 6.3.4 Write the corrected information as close as possible to the lined-out error.

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- 6.3.5 Provide a reason for the error change next to the correction. The reason may also be numbered and described at the bottom of the page or in the comments section of the document. Error explanations, such as “Oops!” or “Wrong.” are inadequate. The reason for the error change must be fully explained.
- 6.3.6 Where insufficient white space permits a fully noted hand change, a common practice is to use an asterisk (or other symbol) near the correction, and elsewhere record the same mark and the notation. A different symbol must be used for each notation to differentiate it from all previous hand changes of the same page. The use of circled incremental numbers (①, ②, ③ etc.) as notation symbols is the preferred practice.
- 6.3.7 It is considered acceptable to make a notation applicable to multiple changes if the notation clearly includes the number of changes that it applies to, such as, “Three entries changed above due to entry errors. KAM 13 Jan 2013.”