



### MRISC STANDARD OPERATING PROCEDURES

<b>SOP Number-version:</b> MRI-4.1	
<b>SOP Title:</b> Good Documentation Practices	
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#### 1.0 Purpose / Scope:

- 1.1 To provide instructions for recording and correcting information and data by researchers at the University of Kentucky MRISC core facility. This procedure applies both to hand-recorded data and to data generated using automated devices.
- 1.2 The scope of this procedure includes all studies conducted on the Siemens 3T PRISMA and Bruker 7T ClinScan small animal MR imager at the UK MRISC.
- 1.3 To help ensure comprehensive traceability and full study or process reconstructability, the MRISC encourages core facility users to thoroughly document (e.g., in the form of a Word file) their specific imaging protocol(s). MRISC staff will help users in doing that.

#### 2.0 Definitions: (if applicable)

For definitions, see the Glossary of Terms located on the GRP Access Server <\\prdlcancifs01.mc.uky.edu\Dept\Neuroscience\GRP> or IP address [\\172.25.104.37\grp\\$](http://172.25.104.37\grp$)

#### 3.0 Specialized Materials & Equipment: (if applicable)

There are no specialized materials and equipment associated with this SOP.

#### 4.0 Procedures:

##### 4.1 Hand-Recorded Data:

- 4.1.1 All data will be written in blue or black indelible ink. Gel pens, pencils, and erasable ink pens are not permitted.

- 4.1.2 Either indelible ink pens or permanent markers (blue or black) may be used to record information on labels for solutions or specimens.
- 4.1.3 All data (including observations and calculations) must be legible.
- 4.1.4 Data must never be obscured. Original entries should not be written or marked over. The appropriate error codes or brief explanation (see below) should accompany any "write-overs".
- 4.1.5 Correction fluid or tape will not be used. Data will not be erased.
- 4.1.6 Original data are never thrown away. All data are retained, even if invalidated.
- 4.1.7 All data should be recorded immediately at the time of the activity or observation.
- 4.1.8 Entries must be signed (initials/personal mark or signature) and dated at the time they are made. Initials/personal mark or signature must be unique and traceable to the individual who made the entry.
- 4.1.9 The following practices are prohibited:
- Back/future -dating (using a past/future date where a current date is required).
  - Documenting an observation or activity prior to performance of the observation or activity.
  - Signing for other personnel (for both data entries and/or correction entries).
- 4.1.10 The following date format is preferred: DD-MMM-YY or DD-MMM-YYYY, where D is the day, M is the month as an abbreviation, and Y is the year (e.g., 31-AUG-2012). Date entries without dashes are also accepted (e.g., DDMMMYY or DDMMMYYYY).
- 4.1.11 When times are recorded the following formats may be used.
- Examples: 1:00 pm or 1:00 p.m., 8:00 am or 8:00 a.m. (12-hr format)  
13:00 or 08:00 (24-hr format)
- NOTE: The 24-hour format is the preferred format.**
- 4.1.12 All data must be recorded directly on the appropriate form. Data must not be written on scrap paper (e.g., Post-its® or paper towels) and then transferred to the appropriate form. If data are accidentally recorded anywhere other than the appropriate form, the original

record must be attached to the form, as it constitutes the original data and an explanation/reference to the original data should be provided for the transposed data on the appropriate form.

- 4.1.13 Ditto marks or equivalent (e.g., arrows) will not be used.
- 4.1.14 All forms will be filled out completely. Blank spaces must not be left on a form.
  - 4.1.14.1 If a form contains space for data that is not applicable, "N/A" or "NA" or a line will be entered in the space.
  - 4.1.14.2 If several spaces of a form or the entire form is not applicable, line(s) may be drawn across the entire unused area with "N/A" or "NA" entered near the line(s).
  - 4.1.14.3 If the information **IS** applicable but the data/information is not available and/or cannot be assessed and there are no other directions provided on the data form to indicate such, use '**NI**' to indicate no information is available.
- 4.1.15 Quantitative values must be recorded numerically as they are observed (e.g., as displayed by the equipment) per NSP-619, Significant Figures and Arithmetic Operations.
- 4.1.16 Units of measurement must be recorded if not indicated on the form.
- 4.1.17 All entries must be an accurate and true representation of observations, information, or data collected during a study. False entries or falsification of entries are prohibited.

#### 4.2 Automated Data:

- 4.2.1 If corrections to electronic raw data cannot be made using an audit trail, then corrections must be made using the print-out of the electronic file.
  - 4.2.1.1 First the original data is printed, and the error is corrected on the print-out with sufficient detail to explain the correction. The print-out contains the initials and date of person recording the data and corrections.
  - 4.2.1.2 The correction is then made to the electronic file, and the corrected data is printed, initialed and dated by the person recording the data.

- 4.2.2 The printed data constitute the original raw data. Examples of such data include that generated by devices such as the N'Vision programmer.
- 4.2.3 All data must be printed at the time of generation. If data are not printed immediately, an explanation will be recorded.
- 4.2.4 All pages of each print-out will be identified with the study number. If not obvious, identification of the device and the test system (animal ID number) will be written on the print-out.
- 4.2.5 All pages of each print-out will be signed or initialed and dated at the time of printing.
- 4.2.6 If data are transferred from the primary computer to a compact disc (CD), the CD will be labeled with the CD's contents, and the label will be signed or initialed and dated by the person transferring the data.

#### 4.3 Correction of Errors:

- 4.3.1 When an error is made or discovered, the error will be corrected. When possible, the person who made the error should make the correction.
- 4.3.2 A person other than the person who made the error may make a correction only if the error is obvious e.g., the information is retrievable from another document.
- 4.3.3 Changes to manual raw data are only to be made by drawing a single line through the original entry, so as not to obscure it, then adding the correct entry.
- 4.3.4 The corrected entry is written next to the original entry or, if space is limited, a footnote may be used.
- 4.3.5 The change or correction must be initialed and dated at the time of correction by the individual making the change, and an explanation (either written-out or coded, see below) must be given for the change.
  - 4.3.5.1 Examples of written-out explanations include: written in wrong entry field, wrong date, and illegible writing.
  - 4.3.5.2 When applicable, the following error codes may be used:

**NOTE: Error codes are circled to be distinguished from personal marks/initials, and placed near the correction. If there is not adequate room**

to legibly place an error code, the correction may be annotated to reference a footnote that contains the error codes or written out explanation(s).

- Ⓜ – **Wrong Location**, data recorded in the wrong location
- Ⓜ – **Wrong Date**
- Ⓜ – **Wrong Time**
- Ⓜ – **Spelling Error**
- Ⓜ – **Calculation Error**
- Ⓜ – **Recording Error** (e.g. illegible, revised for greater clarity etc.)

**NOTE:** Because it is the most general, the **Recording Error** code should not be used where other error codes apply.

**NOTE:** **Recording Error** refers to data entry errors that are not due to calculation, spelling, or location recording errors (e.g., the wrong number was recorded, the numbers were transposed when recorded). A written-out explanation should be used if needed.

- Ⓜ – **Write Over** - inadvertently wrote over the error instead of drawing a line through the error

**NOTE:** **Write-over corrections (“WO”)** should include, to the extent that it is possible, the initial entry written again clearly (in addition to the correct entry).

4.3.6 If the original entry requires verification by a second person, that person must also verify the correction. Re-verification will be documented with signature or initials and date near the corrected entry or, if space is limited, a footnote is acceptable.

**4.4** Late data entries, i.e., those raw data or signatures/initials entered after they were generated, should describe the date the data were generated and the date the entry was made.

- 4.5 Similarly, entries not dated at the time of entry must describe both the date the data were entered and the date the date was entered.
- 4.6 7T MRI Scanner Use and Data Disposition form (see F-MRI-3 Attachment 1 (A1), 7T MRI Scanner Use and Data Disposition)
- 4.6.1 For each animal, enter the date, subject ID, species and time of anesthesia start.
  - 4.6.2 Using the timer, record and initial every 10 minutes the animal's body temperature and respiration rate along with isoflurane anesthesia level and temperature of the bath; heart rate may be required as well.
  - 4.6.3 At the end of anesthesia, turn OFF the anesthesia machine and record the time.
  - 4.6.4 At the end of an MRI scanning session, check that isoflurane, oxygen and the water bath are turned OFF.
  - 4.6.5 Record the level of remaining isoflurane and make an entry of how and where the MRI data has been saved.

**5.0 Attachments:** (if applicable)

There are no attachments associated with this SOP.

**6.0 References:** (if applicable)

6.1 MRI-6.1, Record Retention

6.2 F-MRI-3 Attachment 1 (A1), 7T MRI Scanner Use and Data Disposition

**7.0 Record Retention:**

The Data Disposition Forms are kept by the MRISC.

**8.0 Change History:**

<b>Rev.</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
1	31-May-2020	New procedure