

<b>Title: Good documentation practice</b>	
<b>Effective Date: 1-6-22</b>	<b>Review Date: 1-6-25</b>
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**Document History**

Version	Description of update	Date Effective
1	Change of number for Q-Pulse	2-10-15
2	Reformatted Reference to all recordings being complete and attributable at 3.1 Clarification on the use of coloured ink at 3.9 Clarification of readability and change of standard font at 3.11 Reference to standard version numbering at 3.13 Certified copies at 3.14	1-4-17
3	Updated scope at 1.1 Source Documentation section added from 3.15 Reference to use of eCRF at 3.18 Abbreviations added	1-6-19
4	Clarification that SOP applies to Sponsor QMS documentation at 1.1 Clarification of use of font at 3.11 Reference to 'effective date' at 3.12 Removal of reference to DMC at 3.19	1-6-22

**1. Scope**


1.1 This SOP applies to Sponsor Quality Management System documentation associated with any clinical research project performed within University of Aberdeen (UoA) and NHS Grampian (NHSG) and includes researchers, Research & Development (R&D) staff, Research & Innovations (R&I) staff and Research Governance (RGT) staff.

1.2 The purpose of this SOP is to define acceptable practices for completion of quality records, applicable to the Quality Management Systems (QMS) across UoA and NHSG.

**2. Responsibilities**

Staff involved in clinical research                      To adhere to the requirements of this SOP.


**3. Procedure**

3.1  All records must be attributable, legible and completed at the time of the event (contemporaneously). Records must also be original, accurate and complete. Recording in advance or

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retrospectively (unless written on reflection of an event, or summary of an interview/focus group) is not permitted.

3.2  Data shall be checked to ensure it is correct and that transcription errors have not occurred. Where errors do occur in records or calculations, the original entry must be **crossed out with a single line** and not obliterated, made illegible or deleted. **The correct value must be inserted alongside, and initialled and dated.** All alterations to records must be dated, signed or initialled by the person making them and countersigned by the supervisor required to check them (where appropriate).

3.3  Correction fluid, or equivalent, is **not** permitted for use in any quality records.

3.4  Hand written amendments to controlled documents (eg SOPs) are **not** permitted.


3.5  Ensure that records are not affected by water, light or chemicals resulting in illegibility.

3.6  Explanations in quality records (eg Deviation, Violations etc) must be explicit and attributable.

3.7  Attachments such as printouts from instrumentation, must clearly show traceability and be annotated with date, signature and, where appropriate, a key.

3.8 Where check initials are used, rather than a signature, a record shall exist to demonstrate who the initials belong to (eg a delegation log). Check initials may be used to confirm that:

- All prompts are complete with correct information (eg times, IDs, weights etc).
- Calculations have been carried out correctly and checked.
- That any step checked with initials has been observed and carried out.

3.9  Records must be completed in permanent ink (if the colour of the ink is used as a colour code then this shall be documented), pencil or 'erasable' ink must **not** be used. Consideration of any local requirements for completion of medical forms (eg in black ink) must be made.


3.10 **All** sections of form/checklists must be completed, or an explanation provided as to the reason why a section was not completed. Any prompts that are not applicable shall have 'N/A' recorded.

3.11 For consistency and to improve readability, all controlled documents should be written in 'Calibri' font 11. All controlled documents shall be written in 'plain English' and block capitals shall not be used; where a section requires emphasis **bold** lettering may be used.

Important points may be emphasised with . Warnings may be emphasised with .


Abbreviations may only be used if the full definition is listed on first use within the document.

3.12  All controlled documents shall be paginated (ie detail 'page x of y' in the footer) and include an effective date.

3.13 All controlled documentation shall be version controlled. Draft versions may be listed as 'draft version 1', 'draft version 2' etc. Version numbering shall start with 'V 1' and proceed through 'V 2', 'V 3', 'V 4' etc.  Version numbering shall **never** use decimals (e.g. V 1.1, V 2.3 etc) as this does not permit an adequate audit trail.

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3.14  Where a copy is used to replace an original document, the copy shall be an exact copy and have all the same attributes and information as the original (an electronic document must retain any associated metadata). Consideration must be given to colour copying if the original document was colour coded in any way and all copying processes must be validated. The copy must be verified by a dated signature.

#### Source Documentation

3.15 Good documentation practice ensures that data and study results can be reconstructed. Source data is the original record of data and certified copies of originals that have not been processed.

3.16 Source documents are original documents, data and records, which should be attributable, legible, contemporaneous, original, accurate and complete. Changes to source data shall be traceable ie via a complete verifiable audit trail.

3.17 It is important to establish which documents will be used as source data for a study. A source data list should be created to detail this. An example Source Data Identification list is available on the UoA Clinical Research Governance and Quality Assurance website <https://www.abdn.ac.uk/clinicalresearchgovernance/> - see SOP-QA-28 associated documents.

3.18  If a CRF is to be used as source data then this **must** be confirmed with Sponsor. In addition, an eCRF cannot be considered as source data, unless confirmed with Sponsor.

3.19 Source Data Verification (SDV) is the process of comparing the data entered in the CRF against the source to check for accuracy. SDV shall be carried out in accordance with the agreed study specific monitoring plan (if applicable), in addition to other data checks performed by the Study Team.

## 4. Abbreviations and definitions

CRF/eCRF	Case Report Form/electronic Case Report Form
DMC	Data Monitoring Committee
QMS	Quality Management System
R&D	Research and Development
R&I	Research and Innovation
SDV	Source Data Verification

## 5. Related documentation and references

SOP-QA-1	Management of SOPs
SOP-QA-12	Case Report Forms
TMP-QA-13	Site delegation log
-	University of Aberdeen Style Guide V1 (7/19/2010)

Further details and free guides on plain English are available on [www.plainenglish.co.uk](http://www.plainenglish.co.uk)

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