# STANDARD OPERATING PROCEDURE FOR VERSION CONTROL OF CLINICAL RESEARCH STUDY DOCUMENTATION

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| **SOP NUMBER:** | **Fife R&D SOP04** |
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| **EFFECTIVE DATE:** | **28 July 2021** |
| **REVIEW DATE:** | **28 July 2024** |

## 1. PURPOSE

This document describes the procedure for version control of essential documents used in clinical research studies conducted in NHS Fife.

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via NHS Fife StaffLink, EDGE and the R&D section of the NHS Fife website (www.nhsfife.org/research). For guidance, contact the R&D Department via fife.randd@nhs.scot.

## 2. APPLICABILITY

This SOP applies to clinical research staff and all staff who have responsibility for maintaining version control of clinical research associated documentation.

## 3. POLICY

3.1 Version Control is the management of multiple revisions to the same document. Version control enables us to tell one version of the document from another.

3.2 It is the responsibility of the Chief Investigator/Principal Investigator to ensure all documents have appropriate version control and have been approved by the appropriate parties.

3.3 The Medicine and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA) both require that submitted documents are version controlled.

## 4. PROCEDURE

4.1 For studies Sponsored by NHS Fife, documentation must be version controlled with a version number and version date printed on the document. E.g. *Version 1, Effective date: DD MMM YYYY.* This includes but is not limited to:

- Case Report Forms (CRF)
- Clinical Trial Protocol
- Database Specification Documents
- Data Management Plan
- Documents given to research participants, e.g. Patient Information Sheet, Informed Consent Form, Patient ID Cards and, where applicable, leaflets, posters, patient diaries, etc
- GP letter

- Guidelines
- Logs (delegation, screening, etc)
- Operational Manuals
- Participating Site Agreements
- Prescriptions
- Statistical Analysis Plan
- Supervision Plan
- Trial specific SOP's
- Workflow instructions

4.2 In any application for Sponsorship by NHS Fife, documents must be identified as "draft" in the first instance. Example: "Protocol Draft Version 1: 01.01.2021", the documents may become: "Protocol Draft Version 2: 01.01.2021", "Protocol Draft Version 3: 01.01.2021" etc as account is taken of required changes.

4.3 Once Sponsorship by NHS Fife is confirmed, the word "Draft" is no longer appropriate, and the documents must be updated to Version 1. Example: "Protocol V1: 01.02.2021". This ensures that Version 1 is the document that is submitted with the IRAS application.

4.4 No change can be made to any approved study document without approval of the Sponsor (see R&D SOP20 and R&D SOP40).

4.5 Version numbering should never use decimals (e.g. V1.1, V2.3 etc) as this does not permit an adequate audit trail.

4.6 For studies hosted by NHS Fife, version control must be maintained as above for study documents and templates created locally. This includes but is not limited to:

- Case Report Forms (CRF)
- Guidelines
- Logs (delegation, screening, etc)
- Operational Manuals
- Prescriptions
- Supervision Plan
- Workflow instructions
- Record of Consent Process and Eligibility Confirmation templates

4.7 Previous Versions and amended versions showing track changes all need to be kept and stored, in the Study Master File (Sponsored Studies) and Investigator Site File (hosted studies).

4.8 New versions of approved documents should be documented on the Version Control Log (Doc Ref WI38-02 must be used for Fife Sponsored studies and can be used for hosted studies if the Sponsor does not supply a study specific log). A paper copy of the Version Control Log must be filed at the front of the Study Master File/Investigator Site File (if a Hard Copy File is being used) and an electronic copy stored in the Electronic Site File (on EDGE or in T:\).

## 5. ASSOCIATED DOCUMENTS & REFERENCES

Medicines & Healthcare products Regulatory Agency (MHRA) 'GXP' Data Integrity Guidance and Definitions March 2018
letter (publishing.service.gov.uk)

Health Research Authority – Prepare Study Documentation
Prepare study documentation - Health Research Authority (hra.nhs.uk)

R&D SOP 20 - Management of amendments to Studies Sponsored by NHS Fife.

R&D SOP 40 - Standard Local Management Review of Amendments to Studies.

Doc Ref WI38-02 - Version Control Log

## 6. ABBREVIATIONS

CRF Case Report Forms
GCP Good Clinical Practice
HRA Health Research Authority
ISF Investigator Site File
MHRA The Medicine and Healthcare products Regulatory Agency
R&D Research and Development
REC Research Ethics Committee
SOP Standard Operating Procedure

## 7. DOCUMENT HISTORY

| Version Number: | Edited by (job title): | Effective Date: | Details of Revisions Made: |
|---|---|---|---|
| 1 | Julie Aitken, R&D Trials Facilitator | 31 Oct 2014 | New |
| 2 | Penny Trotter, R&D Quality & Performance Assistant | 28 July 2021 | Updated from WI37 (v1) to SOP04 (v2).<br>Updated to R&D SOP template (v3).<br>Added references for MHRA and HRA.<br>Removed reference to Appendix A of NHS Fife policy GP/R4. |

## 8. APPROVAL

| Approved By | Date |
|---|---|
| Professor Alex Baldacchino, Research & Development Director, NHS Fife<br>Signature:  | 28 July 2021 |