SOP number	**50.017**	Version	**5.0**
Title	**Research & Innovation Document Management**		

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SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Quality Assurance Manager		X		
All Research and Innovation Staff	X			
Chief Investigators				X

1. Scope

This procedure applies to all staff within Clinical Research & Innovation (R&I), covering documents within the QMS and also trial specific document for all study types.

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the requirements and systems in use to manage documents within R&I.

3. Procedures

3.1. Document Control Systems

The following systems are used in R&I to manage internal and external documents:

1.1 Scottish Research Database Application (SReDA)
1.2 EDGE Clinical Research Software (EDGE)
1.3 Shared departmental folders
1.4 Q-Pulse
1.5 HRA Assessment Review Portal (HARP)

Some study documents are stored and shared using SReDA, EDGE and HARP which are all web based systems. Q-Pulse is a Quality Management system used in R&I for, the storage, management and distribution of SOPs and associated documents as well as storage of other document types. This is available in a web based and application format to R&I users on the NHSGGC network. These systems have the following features:

- Documents uploaded and deleted are auditable and reportable
- Consistent structure for all projects
- Reporting of available documents
- Daily back-up

Each department within R&I maintains local shared folders to manage internal and external documents.

Access to all of the above systems are managed based on the need of the individual and have documented processes for granting access.

3.1.1. Trial Master File and Investigator Site File

In addition to the electronic systems mentioned above, a Trial Master File (TMF) and Investigator Site File (ISF) will be in place for each study. For CTIMPs and CIMDs this will be in the form of a printed paper folder(s). All documents within this will be viewed as the master document for the trial, additional copies may exist in other locations but will not be the master. In line with SOP 51.016, the TMF and ISF must be regularly maintained with the appropriate documentation and verified to be accurate and complete before they are added to the folder. For non-CTIMP studies electronic TMFs are acceptable through the use of the common drive, similar electronic systems may be used for the ISF but they must meet the minimum requirements for backup, access rights and traceability.

3.1.2. Trial Specific Websites

On some occasions, an individual trial may wish to create a website for the purposes of sharing documents with trial sites and/or to provide public facing information about the trial. Such a website will only be for the purpose of information sharing and will not replace any existing processes for distributing documentation to sites during initiation or as a result of amendments. The documentation to be retained on any such website will not be the master copy and will not be considered part of the TMF or ISF. All individual websites must have documented instructions on who will maintain the contents and how they will perform QC checks to ensure it is up to date and accurate. Those responsible for maintaining the websites must be appropriately trained in the platform used to host the site and retain evidence of this training. Consideration must be made for the content of the website for impact to the requirements of Copyright, confidentiality (patient identification and sensitivities around IMP or practices), GDPR and avoiding early release of results ahead of publication. In some instances, depending on the nature of what is planned to be placed on the website, REC approval may be required, i.e. advertising for recruitment. All content must comply with NHSGGC Corporate Use of Social Media Policy.

3.2. Controlled Documents

A controlled document is one in which the content must remain consistent and unchanged between versions. The content of a controlled document are used to determine the Quality Management System of the organisation or specific construct and circumstances of a trial.

In order to determine if a document must be controlled, the question must be asked if it is acceptable for the contents to be changed and vary over time without the ability to trace these changes. For example, if a member of staff has their own working document used to track and manage events or activities this does not need to be controlled. If the contents of a document must remain consistent for all users over every iteration and it is required to know the time point at which a change occurs, this must be a controlled document.

If the determination is made that a document is to be controlled, i.e. that its content must remain accessible and consistent to the relevant members of staff across every use then there are certain factors of control which must be maintained.

Controlled documents, such as SOPS, protocols, templates, terms of reference etc., the master copies must:

- Be readily available for those who require its use
- Be stored in such a way that its contents are protected, i.e. avoid use of shared drives. (n.b. if document is to be stored in a shared drive, consideration must be given to read only access or password protection, convert to pdf to prevent editing)
- Be based on an agreed template where available
- Be version controlled

3.2.1. Version Control

Version control of a document is used to identify and differentiate when the content of that document has changed. This is done in absolute terms, for a document to maintain its same ID and Version number it must remain identical in terms of content and format.

If a document is released at version 1, a change as small as correcting a typo or changing a font would result in increasing the version.

The ID of a document will remain associated to all versions of that document, when new versions are released they will be associated to the previous versions to create the complete story of the history of that document, as represented in Figure 1.

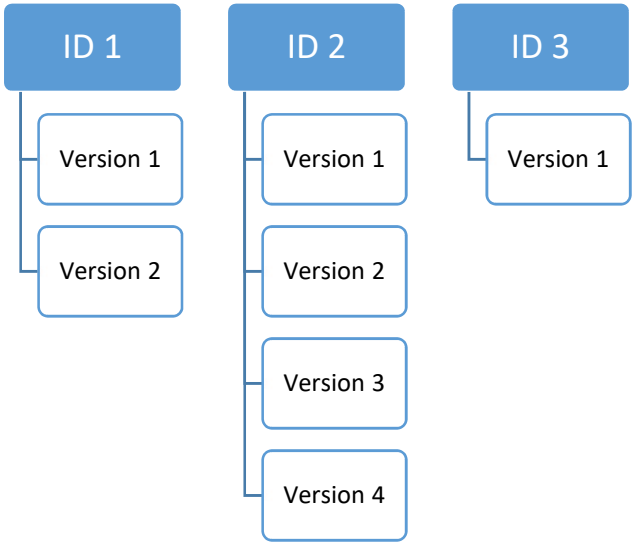

Figure 1 – Version Control

All version controlled documents must go through a controlled approval process in which the contents are reviewed to ensure they are suitable for use and the decision to make the agreed changes are appropriately recorded. Changes to a controlled document must be made or agreed by the owner of the document. The exact approval process will vary depending on the nature of the document, for example SOPs, Forms and Guidelines has a process detailed in SOP 50.023. Study specific documents such as protocol will have their own set criteria of who must approve changes.

The increment with which a version number increases is may be in full numbers or decimal numbers depending on the rules around that particular document type, always refer to the relevant process for the control of the document type in question for guidance. Generally, minor changes to documents such as updating references or links, correcting typos etc will be reflected with 0.1 incremental change. Increase of a version number by a whole number, i.e. 1.0 is usually associated with a more significant change although this is at the discretion of the Author and full number changes may be implemented for all.

3.2.2. Obsolete Documents

In the event a document is being decommissioned or made obsolete, although it's ID number is no longer in the active status it must remain to be viewed across the timeline of its use.

The ID number of decommissioned documents will not be eligible to return to circulation for use on other documents as it must be viewed in this entire lifecycle and will always be associated with and viewed as a continuation of the original document. This is different from releasing a new version in which the previous version is removed from circulation. When a document is decommissioned or made obsolete, the entire document ID and all associated versions are no longer in use.

Not all documents are eligible to be made obsolete, e.g., study specific documents like protocols - the process for release of new versions will only be relevant.

3.2.3. Certified Copies

On occasion it will be required to make a copy of a document and for this copy to then be seen as the master document, this may be from making a photocopy on to paper or scanned to a pdf. In this event, the individual that has made the copy must ensure that the copy is an accurate representation of the original and document that the copy has been made and verified as accurate. For medical records, a system is in place by the central scanning team to document this information and similarly for some sites within NHSGGC local processes will be in place and staff will be trained on this.

When ensuring a copy is accurate the following must be considered:

1. Are all pages present
2. Is the copy legible
3. Has an information been obscured

When making a photocopy, the individual copying must either stamp, initial or mark the document to show it has been verified. For PDF copies, it is the responsibility of the individual to verify it is an accurate copy before saving it.

3.3. Uncontrolled Documents

For day to day operation and sharing of information, uncontrolled documents may be used. It is important to identify what the master copy of a document is using the criteria detailed above. Any copies of a master document which do not meet the above control criteria must be identified as uncontrolled copies, staff should always make efforts to ensure they are using the most up to date and controlled version of a document. To this end, avoid practices such as:

- Using stored local copies on own computer
- Using printed copies of documents
- Using documents sent to you previously after a significant period of time has passed

Efforts must be made at all times to identify and refer to the master document when using its content.

3.4. Formatting Standards

All controlled documents and templates must be consistent in the identifiable features they contain. At a minimum, all controlled documents must contain:

Item	Location
Page # of #	Footer
Version number	Header or Footer
Date of Version release	Anywhere within document
Author	Anywhere within document
Document History*, **	End of Document

Table 1 – Features of a Controlled Document

Additional considerations:

- Add the version number to the electronic file title
- *Document history/version control table describing the purpose for the change is mandatory for some documents e.g. SOPs but may not be for some locally produced documents. However if not in the document a change control log should be maintained for the document locally.
- **Document history is only required to be present on a master copy of Forms held in Q-Pulse, versions with this removed will be made available for use through Q-Pulse and the website.
- SOPs, Forms and Guidelines must have a footer highlighting that it is a controlled document and is no longer considered to be controlled when printed. This is part of the standard template for these documents.

For Standard Operating Procedures and their associated forms and guides, SOP 01.005, SOP 01.006 and SOP 50.023 must be followed.

4. Referenced documents

- SOP 50.023 - Management of SOPs within NHS GG&C R&I
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 01.005 - Format of Standard Operating Procedures and Related Documents
- SOP 01.006 - Production and Maintenance of Standard Operating Procedures and Related Documents

5. NHSGGC Corporate Use of Social Media Policy.- www.nhsggc.org.uk/media/256827/policy-on-corporate-use-of-social-media-final-november-2019.docxRelated documents

- N/A

6. Document history

Version	Date	Description
1.0	14/07/2016	SOP creation
2.0	19/12/2018	Staff category updated
3.0	11/12/2019	Inclusion of version control procedure
4.0	05/10/2022	Change of author, reformat and expanded detail
5.0	14/05/2025	Inclusion of certified copies, specific reference to TMFs/ISFs and Trial Specific Websites.