Standard Operating Procedure			**50.017**
Clinical Research & Innovation Document Management			
Version	**4.0**		
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Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C General

2. Staff Category

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

3. Scope
This procedure applies to all staff within Clinical Research & Innovation

4. Purpose
The purpose of this Standard Operating Procedure (SOP) is to describe the requirements and systems in use to manage documents within Clinical Research & Innovation.

5. Procedures
5.1. Document Control Systems
The following systems are used in Clinical Research & Innovation to manage internal and external documents:

- Scottish Research Database Application (SReDA)
- EDGE Clinical Research Software (EDGE)
- Shared departmental folders
- Q-Pulse
- 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 GG&C 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 Clinical Research & Innovation 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.

5.2. 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 the 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

5.2.1. 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.

5.2.2.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.

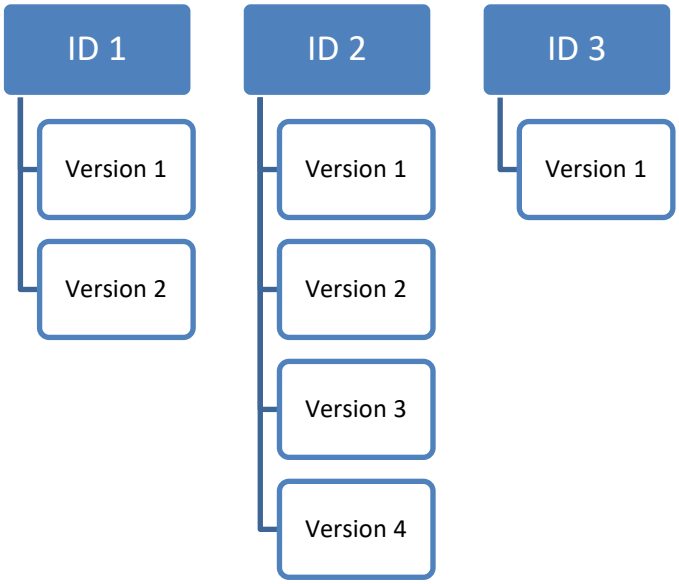

Figure 1 – Version Control

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.

5.2.3.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.

5.3. Formatting Standards

All controlled documents and templates for their production 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 eg 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.

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

6. Referenced documents

- SOP 01.005 - Format of Standard Operating Procedures and Related Documents
- SOP 01.006 - Production and Maintenance of Standard Operating Procedures and Related Documents
- SOP 50.023 – Management of SOPs within NHS GG&C R&I

7. Related documents

- SOP 51.001 Protocol development

8. 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