Preparation, Maintenance and Control of Standard Operating Procedures and Related Documentation

SOP ID: SHLS-S-001 V2.0

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Document History

Version	Description of Update	Date Effective
2.0	Periodic Review	02/04/2024
1.0	First Release	03/09/2020

1. Purpose

1.1 To document the procedure for preparation, control and maintenance of SOPs that encompass all clinical research within GCU SHLS.

2. Scope

2.1 All GCU SHLS staff members involved in the preparation, control, maintenance, implementation and use of clinical research governance SOPs.

3. Responsibilities

3.1 The SCRGM is responsible for the control of SOPs and related forms, templates and guidance documents.

3.2 The SOP author is responsible for consulting relevant staff, regulations and GCU policies in the preparation of SOPs, forms, templates and guidelines.

3.3 SHLS staff members undertaking clinical research are responsible for reading SOPs and associated documents and informing the SCRGM of any changes required to existing documents or proposals for new SOPs.

3.4 The Approver is responsible for providing sign off on new and amended SOPs and attached documents.

4. Procedures

4.1 Definitions

4.1.1 SOPs are controlled documents that ensure documented processes/procedures are in place to comply with clinical trial legislation, best practice and wider GCU policies. The language used within an SOP shall ensure the reader understands the scope of the process being described. Mandatory process steps are indicated by the use of definitive language such as will, are, must or essential. Non-mandatory process steps are indicated by the use of advisory language such as should, can or may.

4.1.2 Guidelines are supporting documents that provide extra detail to the process outlined within an SOP.

4.1.3 Forms are provided when a process defined within an SOP requires all SOP users to conduct the task in the same manner.

4.1.4 Templates are documents provided as an example of best practice. Users may choose to use the template to carry out their task or to adapt the template document to suit their needs.

4.2 Creation of New SOPs, Guidelines, Templates and Forms

4.2.1 Any member of staff can suggest new SOPs and associated documentation by emailing the SCRGM form SHLS -F-001A. The SCRGM will then determine the need for the document and identify the most appropriate author.

4.2.2 The new SOP author will receive template SOP form SHLS-F-001B to create a concise, clear SOP and supporting documentation as required.

4.2.3 The new SOP and associated documents will be approved by the School Research Committee.

4.2.4 Any changes required will be completed by the author.

4.2.5 Once all parties agree the content of the final version of the SOP and/or supporting documents it shall be signed by the author and approver. The date of the signatures is the 'release' date.

4.2.6 Wet ink signature copies of SOPs will be held by the SCRGM or delegate. Electronic versions will note that the signature is held on file.

4.2.7 Implementation date shall be 6 weeks after release date to provide staff groups time to review the new documents.

4.2.8 SOPs and supporting documents will be published on the GCU website.

4.3 Modification of SOPs, Guidelines, Templates and Forms

4.3.1 Any member of staff can suggest modification to SOPs and associated documentation by emailing the SCRGM form SHLS-F-001A. The SCRGM will then determine the need for the update. If the modification is deemed minor this update will be held on a log maintained by the SCRGM until the next periodic review (4.5). If the update is essential to the scope of the SOP or associated documents, then the author will be contacted to request an update to the documentation.

4.3.2 Steps 4.2.3 to 4.2.8 will be followed.

4.3.3 In the event that the update to the SOP is determined to be urgent the review process can be bypassed by the author after discussion with the SCRGM and Approver. For urgent updates the implementation date shall be 3 weeks from authorisation.

4.3.4 Minor updates to SOPs and related documents shall see the version change from 1.0 to 1.1 as example. Major changes to process shall see the SOP update from 1.0 to 2.0.

4.3.5 All updates to the SOP whether major or minor shall be detailed within the 'Description of Update' section.

4.4 Making SOPs, Guidelines, Templates and Forms Obsolete

4.4.1 As research legislation, processes and policy change there may be instances where SOPs become obsolete. Any member of staff can put forward a document they think requires to be made obsolete. The SCRGM will review the SOP and/or associated documents to determine the requirement to remove it.

4.4.2 Any SOP made obsolete will be recorded on the obsolete SOP tracker held by the SCRGM including the reasons as to why it was removed from circulation.

4.4.3 Wet ink versions of SOPs and associated documents will be held by the SCRGM indefinitely.

4.5 Periodic Review of SOPs

4.5.1 SOPs and attached documentation will be reviewed at least every 4 years from the latest implementation date.

4.5.2 Any updates required to an SOP, guideline, template or form will follow section 4.3

5. Referenced and Related Documents

- SHLS-F-001A: Document Changes Request Form
- SHLS-F-001B: SOP Template
- SHLS-F-001C Form, Guideline and Template Sign off

6. Abbreviations and Definitions

GCU - Glasgow Caledonian University
SCRGM – Senior Clinical Research Governance Manager
SHLS - School of Health and Life Sciences
SOP - Standard Operating Procedure