Study Documents	
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Document History

Version	Description of Update	Date Effective
2.0	Periodic Review	02/04/2024
1.0	First Release	01/03/2021

1. Purpose

1.1 To describe the procedure for preparing study documents in accordance with GCP and applicable regulatory requirements for clinical research projects.

2. Scope

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

3. Responsibilities

3.1 The CI, or designee, is responsible for ensuring all clinical research documentation adheres to regulatory requirements and GCP.

3.2 The PI, or designee, is responsible for ensuring all study team members are trained in the study documentation for a research project and ensuring all documentation is maintained.

4. Procedures

4.1 Study documents must be approved by GCU REC and then NHS REC.

4.2 Any amendments to patient documents must receive appropriate regulatory body approval before use. Further information regarding the amendment process can be found at: IRAS – Maintaining Your Approvals.

5. Referenced and Related Documents

- SHLS-T-004A: SHLS Patient Information Sheet Template
- SHLS-T-004B: HRA Patient Information Sheet Template
- SHLS-T-004C: Consent Form Template
- SHLS-T-004D: HRA Qualitative Protocol Development Tool
- SHLS-T-004E: GP Letter Template
- SHLS-T-004F: Site Screening and Enrolment Log
- SHLS-T-004G: Study Specific Training Log
- SHLS-T-004H: Delegation Log
- SHLS-T-004I: File Note

6. Abbreviations and Definitions

CI – Chief Investigator
GCP – Good Clinical Practice
GCU REC – Glasgow Caledonian University Research Ethics Committee
NHS REC – NHS Research Ethics Committee
PI – Principle Investigator
SHLS – School of Health and Life Sciences