

Study Documents	
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Document History

Version	Description of Update	Date Effective
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.

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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 GCU REC and NHS REC approval before use.

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

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